

The Law of Placenta

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ABSTRACT: Of the forms of reproductive labor in which legal scholars have been interested, placenta, the organ developed during pregnancy, has been overlooked. As placenta becomes an object of value for a growing number of individuals, researchers, clinicians, biobanks, and biotech companies, among others, its cultural meaning is changing. At the same time, these various constituencies may be at odds. Some postpartum parents and their families want to repossess their placenta for personal use, while third parties use placentas for a variety of research, medical, and commercial purposes. This Article contributes to the scholarship on reproductive justice and agency by asking who should have access to placentas and under what conditions. The Article emphasizes the insufficient protection the law affords pregnant people wishing to decide what happens to their placenta. Generally considered clinical waste under federal and state law, placental tissue is sometimes made inaccessible to its producers on the ground that it is infectious at the same time as it is made available to third parties on the ground that placenta is discarded and de-identified tissue. Less privileged people who lack the ability to shop for obstetric and other pregnancy-related services that allow them to keep their placentas are at a disadvantage in this chain of supply and demand. While calling for further research on the modus operandi of placenta markets and how pregnant people think about them, this Article concludes that lawmakers should take steps to protect decision-making autonomy over placental labor and offers a range of proposals to operationalize this idea.

For helpful conversations and comments on earlier drafts, I am grateful to Lynn Borgatta, Courtney Cahill, Bridget Crawford, Amy DiBona, Greer Donley, Elizabeth Emens, Clare Flannery, Rachel Goldstein, Harvey Kliman, Kimberly Krawiec, Mathieu Morin (Department of Research in Obstetrics and Gynecology, Toulouse University Hospital, France), Lauren Perley, Stephanie Schiavenato, Michelle Silasi, and Leigh Turner, as well as participants in the NYU Anthropology Department Faculty Colloquium, the 2019 Baby Markets Roundtable, and the *Yale Journal of Law and Feminism* Workshop. For research assistance, I thank Megan Grant and Ciarra Minacci-Morey. For library assistance, I thank the University of Connecticut law library staff, in particular Tanya Johnson, who provided exceptional library and research assistance. Finally, many thanks to Sophie Laing and Lauren Blazing of the *Yale Journal of Law and Feminism* for their feedback and suggestions.

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INTRODUCTION

When we think about or describe childbirth, we typically have in mind the process that begins with labor and ends with the birth of a baby. We rarely consider what happens after the baby is born, yet anyone familiar with childbearing knows that what follows: the so-called “third stage of labor” is the delivery of the placenta or afterbirth. The birthing person’s uterus continues to contract to push out the placenta, which is usually delivered fifteen to thirty minutes after the baby.¹ Often ignored or treated as a waste product to be discarded, the placenta is typically not the focus of attention among parents, maternity-care professionals, or legal scholars.² Yet the social life of placentas barely begins with pregnancy.³ Some placentas are destroyed by healthcare facilities, but others are eaten, buried, planted, or transformed into art, while still more are banked, used for research, or made into prized components in medical, health, and cosmetic treatments. Though it is difficult to trace their paths, as little information is publicly available, the circulation of placentas outside of pregnant bodies across the bioeconomy raises a number of factual and legal questions. Who decides the fate of placentas? How are placenta supply chains regulated? Do placenta markets raise new questions or do they duplicate the characteristics of other markets for human tissue?

Rebecca Skloot’s *The Immortal Life of Henrietta Lacks* has generated significant attention and debate around the property and privacy rights of patients when their data and tissues are appropriated by healthcare providers, earning the providers reputational and financial benefits about which patients often are not aware and from which they do not benefit.⁴ What is unique about the placenta, as opposed to other tissues, is that it has practical as well as spiritual and cultural uses for the person who grows it and their family, as well as scientific, clinical, and commercial potential for third parties such as researchers, clinicians,

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1. Throughout the Article I strive to use gender-neutral language to designate the producers of placentas in recognition that people who do not identify as women or as any gender grow placentas and may have an interest in them. I occasionally use the word woman and other gendered terms when paraphrasing others or to emphasize the female coding of placental labor in our culture and its attendant subordination.
 2. *But see* Elizabeth Kukura, *Obstetric Violence*, 106 GEO. L.J. 721, 730, 734, 735 (2018) (mentioning the unconsented manual removal of placenta by medical personnel as an element of obstetric violence).
 3. *See* THE SOCIAL LIFE OF THINGS: COMMODITIES IN CULTURAL PERSPECTIVE (Arjun Appadurai ed., 1988) (showing that things lead social lives through the meanings people attribute to them in their uses and transactions).
 4. Henrietta Lacks was a poor, Black woman and tobacco farmer whose contribution to medicine had gone unrecognized. In 1951, Lacks’s cervical cancer cells served to create the first immortal cell line, called the HeLa line, which became invaluable for research. Her cells led to several medical breakthroughs, served as the basis for several thousands of patents, and generated drug companies billions of dollars in profits. Lacks was the unwitting source for these cells and did not benefit medically or financially from any of these discoveries. *See* REBECCA SKLOOT, *THE IMMORTAL LIFE OF HENRIETTA LACKS* (2010).

biobanks, biotech companies, and drug and cosmetic companies.⁵ Patients rarely ask for their excised body parts to be returned to them after a diagnostic or medical procedure (though some amputees have been known to request and obtain their limbs to take home).⁶ But in many cultures, including Native American cultures such as the Navajo,⁷ the placenta has long been saved for ritual purposes, and a growing number of postpartum parents from diverse backgrounds seek to repossess their placenta to bury it, eat it, or bank it. Individuals' interests in their placentas have disruptive effects on the market for placentas. These interests are less salient in other body markets, such as those of blood, semen, or organs, in which donors typically do not seek to repossess their own materials for self-consumption. By taking their tissue out of the supply and demand chain, patients who claim their placenta expose the irony of the dominant legal characterization of placentas (and other excised body parts) as "medical waste" when in reality they are in high demand for a variety of uses.

Placental tissues not only are collected at the end of a pregnancy, but also are collected from leftover tissues following prenatal tests or surgical procedures conducted for pregnancy termination or loss.⁸ The wide range of sources for placental tissue implies that the majority of people who can become pregnant are, have been, or will be in a position to donate their placenta during their reproductive years. Those who have undergone a chorionic villus sampling (CVS test, a prenatal diagnostic test to detect congenital abnormalities in the fetus by removing and analyzing a small placenta sample),⁹ experienced dilation and curettage (D&C) or dilation and evacuation (D&E) following a miscarriage, had a surgical abortion, or delivered a baby, may have relinquished parts or the entirety of their placenta at the healthcare facility unless they purposefully

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5. That said, instances of self-eating have been reported for virtually every body part, as a medicinal practice or as a form of pathology. See Mathilde Cohen, *The Law of Self-Eating: The Consumption of Milk, Placenta, and Feces* (Sept. 30, 2018) (unpublished manuscript) (on file with the author).
 6. Kristin Hugo, *She Took Her Amputated Leg Home, and You Can Too*, PBS (Jan. 4, 2017, 5:38 PM EST), <https://www.pbs.org/newshour/science/took-amputated-leg-home-can> [<https://perma.cc/3BV5-ZFEP>]; see also Margaret Atwood, *Kat*, NEW YORKER, Mar. 5, 1990, at 38 (a short story in which the main character, Kat, takes home her ovarian tumor after surgical removal, preserving it in formaldehyde, displaying it on her mantelpiece, and naming it Hairball).
 7. See Louise Lamphere, *Migration, Assimilation and the Cultural Construction of Identity: Navajo Perspectives*, 30 ETHNIC & RACIAL STUD. 1132, 1141 (2007).
 8. See Judith E. Cartwright & Guy StJ. Whitley, *Strategies for Investigating the Maternal-Fetal Interface in the First Trimester of Pregnancy: What Can We Learn About Pathology?*, 60 PLACENTA 145, 147 fig.1 (2017) (discussing the question of "[t]issue accessibility at different stages of pregnancy" and the "limitations and advantages" of what can be studied from tissue obtained at different stages).
 9. See Giovanni Monni, Rosa Maria Ibba, & Maria Angelica Zoppi, *Prenatal Genetic Diagnosis through Chorionic Villus Sampling*, in GENETIC DISORDERS AND THE FETUS: DIAGNOSIS, PREVENTION AND TREATMENT 160 (Aubrey Milunsky & Jeff M. Milunsky eds., 6th ed. 2010) (describing chorionic villus sampling (CVS), a procedure involving a biopsy of the placenta, which is usually performed during the first trimester of pregnancy to diagnose certain genetic or chromosomal disorders).

obtained it for themselves. Considering that, in the United States, 86% of women aged 40 to 44 are mothers,¹⁰ nearly 1 in 4 women (23.7%) will have an abortion by age 45,¹¹ and miscarriages occur in 10 to 25% of known pregnancies,¹² it may well be that the vast majority of people who were ever pregnant have (wittingly or unwittingly) contributed placental tissues to placenta markets.¹³

This Article exposes the insufficient protection afforded by the law to people wishing to have agency over their placental labor, an often-overlooked dimension of reproductive labor. Under federal and state laws, placental tissue is typically treated as medical waste and disposed of according to standard waste management procedures.¹⁴ Because placentas usually contain no identifiers linking them to particular donors, they can be used for research without requiring donors' consent.¹⁵ Healthcare facilities can also donate them to biobanks or procurement organizations for clinical or commercial uses. That being said, there has been progress toward the legal recognition that individuals may have special interests in their placentas. In traditional Hawaiian culture, the proper care of the placenta of a newborn has tremendous cultural and spiritual significance—it must be buried, usually under a tree, to keep the child connected to its home.¹⁶ When the State of Hawai'i declared the placenta to be infectious waste in 2005, Native Hawaiian groups fought back successfully. As a result, in 2006 the state became the first in the nation to statutorily protect the right of birthing parents to repossess their placenta following a hospital birth.¹⁷ Since then, though hospitals

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10. Claire Cain Miller, *The U.S. Fertility Rate Is Down, Yet More Women Are Mothers*, N.Y. TIMES (Jan. 18, 2018), <https://www.nytimes.com/2018/01/18/upshot/the-us-fertility-rate-is-down-yet-more-women-are-mothers.html> [https://perma.cc/4LS2-9YM2].
 11. Rachel K. Jones & Jenna Jerman, *Population Group Abortion Rates and Lifetime Incidence of Abortion: United States, 2008–2014*, 107 AM. J. PUB. HEALTH 1904 (2017).
 12. *Miscarriage: Signs, Symptoms, Treatment, and Prevention*, AM. PREGNANCY ASS'N, (Oct. 10, 2019, 2:02 PM), <https://americanpregnancy.org/pregnancy-complications/miscarriage> [https://perma.cc/JQ9Y-DWPF].
 13. See, e.g., Steven Petrow, *Who Owns Your Medical Data? Most Likely Not You*, WASH. POST (Nov. 25, 2018, 6:00 AM MST), https://www.washingtonpost.com/national/health-science/who-owns-your-medical-data-most-likely-not-you/2018/11/23/28785efc-e77d-11e8-a939-9469f1166f9d_story.html [https://perma.cc/8E9H-GBEZ] (reporting that healthcare facilities typically require that patients admitted for treatment or testing sign blanket consent forms giving the doctor or institution permission to use their data or tissue samples as they see fit without having to notify or compensate them and noting that health data is routinely sold or licensed to commercial, for-profit companies).
 14. See *infra* Part II.A.1.
 15. See Rebecca Scott Yoshizawa et al., *Postpartum Women's Perspectives on the Donation of Placentas for Scientific Research in Campinas, Brazil*, 10 J. EMPIRICAL RES. ON HUM. RES. ETHICS 76, 77 (2015) (citing scientists who reported using placentas without explicit, informed consent because placentas are "considered a throwaway tissue"); see also *infra* Part III.B.1.
 16. See Melody Kapili'alo'ha MacKenzie, *Hawaiian Custom in Hawai'i State Law*, 13-14 Y.B. N.Z. JURIS. 112, 149 (2010-2011).
 17. See Nancy Cook Lauer, *Hawaiian Law Now Permits Parents to Keep Placentas*, WOMEN'S ENEWS (July 28, 2006), <https://womensenews.org/2006/07/hawaiian-law-now-permits-parents-keep-placentas> [https://perma.cc/MGR5-H6VL].

and birthing centers around the country have become more lenient in releasing placentas, some still refuse or make it so difficult that they interfere with birthing parents' planned use. For instance, in 2016, Jordan Thiering, a pregnant Mississippi woman, found out that the hospital where she planned to deliver considered placentas medical waste which could not be released without a court order.¹⁸ She made the national headlines by going to court to obtain the order to take her placenta home. Meanwhile, placentas have become embroiled in abortion wars with the passage of state fetal burial laws, which prohibit abortion providers from disposing of fetal remains as they would surgical waste.¹⁹ The result is that in some states individuals have more access to their placenta in the context of an abortion or miscarriage than a live birth, evidencing the entanglement between the law of placenta and reproductive justice.

There is little predictability or clear information available on whether and how people can retain their placentas, which are defined and regulated by a patchwork of federal and state regulations related to medical waste, anatomical gifts and tissues, food and drug laws, cord-blood donation programs, and cosmetics regulation, among other sources of law. Even less is known about how discarded placentas circulate among medical facilities, researchers, biobanks, procurement organizations, and other stakeholders.²⁰ Legal scholarship is practically nonexistent on the topic of placentas in the United States. To the best of my knowledge, only three law review articles specifically address placentas, all focusing on the regulation of placentophagy, that is, whether and how women should be allowed to eat their own placentas.²¹

This Article is the first to provide a comprehensive legal analysis of the various uses and modes of consumption of placentas today. It builds upon two strands of feminist scholarship. First, the analysis of placenta markets is inspired by legal scholars such as Donna Dickenson²², Michele Goodwin,²³ Kimberly

18. See Corky Siemaszko, *Pregnant Mississippi Woman Wins Court Fight for Her Placenta*, NBC NEWS (June 5, 2016, 9:43 AM MST), <https://www.nbcnews.com/news/us-news/pregnant-mississippi-woman-wins-court-fight-her-placenta-n584846> [https://perma.cc/3D6W-XMSC].

19. See *infra* Part II.B.3.

20. Because placenta is collected, processed, and marketed by live industries at the forefront of research, an added challenge to the lack of publicly available information is the constantly changing nature of the markets. My learning about the topic will continue and I welcome input from stakeholders.

21. See Carmen M. Cusack, *Placentophagy and Embryophagy: An Analysis of Social Deviance Within Gender, Families, or the Home (Etude 1)*, 1 J.L. & SOC. DEVIANCE 112 (2011) (arguing that placentophagy and embryophagy are not illegal); Greer Donley, *Regulation of Encapsulated Placenta*, 86 TENN. L. REV. 225 (2019) (considering the legal implications of placenta encapsulation); Amber Goeden, *Placentophagy: A Woman's Right to Her Placenta*, 3 CONCORDIA L. REV. 170 (2018) (regulation of placentophagy).

22. DONNA DICKENSON, *PROPERTY IN THE BODY: FEMINIST PERSPECTIVES* (2007).

23. THE GLOBAL BODY MARKET: ALTRUISM'S LIMITS (Michele Goodwin ed., 2013).

Krawiec,²⁴ Judit Sándor,²⁵ Radhika Rao,²⁶ Kara Swanson,²⁷ and Catherine Waldby and Melinda Cooper²⁸ who theorize human body markets and the rise of biocommodities regulation. Their writing explores the gender inequities as well as other forms of intersectional oppressions underlying these markets and the changing dynamics of value for female embodied labor. Second, I draw on scholarship on women's distinctive experiences with their placentas. The scientific, social science, and humanities literature on placentas has grown dramatically in the past decade, with pioneering work in particular by sociologists Julie Kent and Rebecca Yoshizawa,²⁹ cultural studies scholar Charlotte Kroløkke,³⁰ geographer Maria Fannin,³¹ and philosopher Cressida Heyes,³² whose writings make visible the feminized form of reproductive labor at stake in placenta markets. In different ways, these scholars critique the erasure of women's work in the matter of reproduction, emphasizing that pregnant people are not passive objects or containers from which doctors pull out children and tissues such as placentas.

The Article proceeds in three Parts. Part I situates placentas in society and biomedicine, presenting their uses by various stakeholders and the discourses surrounding them. Part II turns to the law, exploring some of the inequities of the placental economy, including the barriers preventing some individuals from repossessing their own placentas when third party actors enjoy relatively easy access. By placental economy, I mean the circulation of placentas outside of pregnant bodies from healthcare facilities to third parties and to consumers—including back to women themselves as consumers. Part III advocates in favor of granting individuals more control over their placentas, identifying possible

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24. Kimberly D. Krawiec, *A Woman's Worth*, 88 N.C. L. REV. 1739 (2010) (proposing the notion of "taboo trades" in the context of body product markets).
 25. Judit Sándor, *Commodified Bodies: Is It a Gender Issue?*, in *NEW CANNIBAL MARKETS: GLOBALIZATION AND COMMODIFICATION OF THE HUMAN BODY* 325 (Jean-Daniel Rainhorn & Samira El Boudamoussi eds., 2015).
 26. Radhika Rao, *Informed Consent, Body Property, and Self-Sovereignty*, 44 J.L., MED. & ETHICS 437, 440 (2016).
 27. Kara W. Swanson, *Rethinking Body Property*, 44 FLA. ST. U. L. REV. 193 (2016).
 28. Catherine Waldby & Melinda Cooper, *The Biopolitics of Reproduction: Post-Fordist Biotechnology and Women's Clinical Labour*, 23 AUSTL. FEMINIST STUD. 57 (2008); Catherine Waldby & Melinda Cooper, *From Reproductive Work to Regenerative Labour: The Female Body and the Stem Cell Industries*, 11 FEMINIST THEORY 3 (2010).
 29. See, e.g., R.S. Yoshizawa, *Review: Public Perspectives on the Utilization of Human Placentas in Scientific Research and Medicine*, 34 PLACENTA 9 (2013).
 30. CHARLOTTE KROLØKKE, *GLOBAL FLUIDS: THE CULTURAL POLITICS OF REPRODUCTIVE WASTE AND VALUE* (2018).
 31. Maria Fannin, *Placental Relations*, 15 FEMINIST THEORY 289 (2014); Maud Perrier & Maria Fannin, *Belly Casts and Placenta Pills: Refiguring Postmaternal Entrepreneurialism*, 31 AUSTL. FEMINIST STUD. 448 (2016).
 32. Cressida Heyes, *Placenta-Eating and the Epistemology of Ignorance*, 37 ATLANTIS 111 (2016).

choice architectures to that end, and examines avenues to regulate third parties' access to and use of placentas.

I. THE USES OF PLACENTA

This Part describes the various purposes for which placentas are used, be it by birthing parents and their families or by third parties such as researchers, clinicians, biobanks, biotech, drug, and cosmetic companies. Before detailing these usages, this Part provides an overview of the placenta as an organ.

The placenta is a critical but temporary organ, which develops as a result of pregnancy and undergoes structural and functional changes throughout gestation.³³ A term placenta delivered following thirty-seven to forty-two weeks of pregnancy typically weighs about a pound and is roughly the size of a small dinner plate.³⁴ The placenta is often presented as a major “interface” between the pregnant person and the fetus.³⁵ Over the course of a pregnancy, its principal function is to supply the fetus with oxygen and nutrients, protect the fetus from environmental exposures by serving as a crossing guard for substances travelling between woman and fetus, and remove waste products. In a way the placenta acts as every organ the fetus needs to survive—heart, lungs, gut, liver, even the endocrine system—producing nutrients, enzymes, and hormones;³⁶ removing waste; providing a barrier against viruses and bacteria; and passing along essential antibodies.³⁷ The placenta impacts the pregnant person, affecting their metabolism and fending off dangers such as viral infections.³⁸ Despite the placenta's importance in the health of women and fetuses, in-depth understanding of its function and properties is still lacking. In 2014, the National Institute of Child Health and Human Development (NICHD) launched a multi-disciplinary project called the “Human Placenta Project” to address this lack of knowledge.³⁹

33. Graham J. Burton & Abigail L. Fowden, *The Placenta: A Multifaceted, Transient Organ*, PHIL. TRANSACTIONS ROYAL SOC'Y B, Mar. 2015, at 1; see also Kurt Benirschke, *Remarkable Placenta*, 11 CLINICAL ANATOMY 194, 196 (1998) (noting that three principal tissues make up the placenta: (1) the trophoblast, (2) connective tissue with chorionic membrane and blood vessels, and (3) the amnion).

34. See Burton & Fowden, *supra* note 33, at 2.

35. See Rebecca Scott Yoshizawa, *Fetal–Maternal Intra-action: Politics of New Placental Biologies*, 22 BODY & SOC'Y 79 (2016) (critiquing the notion of the fetal-maternal interface for presuming a separation between “mother” and “fetus”).

36. MICHAEL L. POWER & JAY SCHULKIN, *THE EVOLUTION OF THE HUMAN PLACENTA* 166–67 (2012).

37. See Burton & Fowden, *supra* note 33, at 375.

38. *Id.* at 371.

39. *Human Placenta Project*, EUNICE KENNEDY SHRIVER NAT'L INST. CHILD HEALTH & HUM. DEV. (Oct. 31, 2018), <https://www.nichd.nih.gov/research/supported/HPP/default> [<https://perma.cc/AA75-PK7X>].

Historically, medical practitioners, religious authorities, and philosophers have been divided as to whether the placenta belongs to the pregnant person or to the fetus. The placenta is composed of both maternal and fetal tissues, but from a regulatory perspective it is not considered fetal tissue and thus is exempt from the strict federal legal regime governing fetal tissue donation and research.⁴⁰ According to philosopher Cressida Heyes, “[t]he body of the mother/fetus is neither self-evidently one nor two and the placenta is the liminal organ through which that mutual incorporation is most apparent.”⁴¹ The placenta challenges our way of classifying the world and its inhabitants into separate beings with their own distinct bodies and organs. In some cultures, the placenta is considered a twin, sibling, or friend to the fetus/child, in others, it is thought to harbor the power to protect and heal the living body, to be related to fertility, to connect newborns to their place of birth, to establish fatherhood, among other functions.⁴² As soon as a baby is born in the United States, the placenta is disconnected from them by cutting the umbilical cord, suggesting a cultural commitment to an ontology of separation, though delayed clamping has grown in popularity.⁴³ Typically, the placenta is removed or caught by the birth attendant, depending on whether the delivery is vaginal or via C-section. It is often discarded as its biologic function has been accomplished and it no longer appears useful. Yet a growing number of parents and their families question this course, seeking to repossess their placenta so as to make use of it.

A. Self-Consumption

Postpartum people and their families consume their placentas in three main ways. First, in certain cultures and communities, placentas have a social, religious, or spiritual significance dictating that the postpartum woman and her family accomplish a number of rituals with them. Second, a rising trend is for birthing parents to eat their placenta or employ it in other Do-It-Yourself (“DIY”) ways. Third, new parents can bank their placenta for future use.

40. The law governing fetal tissue donation and research defines “human fetal tissue” as “tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth.” 42 U.S.C. § 289g-1(g); see also V. Noah Gimbel, *Fetal Tissue Research & Abortion: Conscriptio, Commodification, and the Future of Choice*, 40 HARV. J.L. & GENDER 229, 235-37 (2017) (examining critically the federal requirements governing fetal tissue donation and research).

41. See Heyes, *supra* note 32, at 113.

42. Gwynne L. Jenkins & Jeremy Sugarman, *The Importance of Cultural Considerations in the Promotion of Ethical Research with Human Biologic Material*, 145 J. LABORATORY & CLINICAL MED. 118, 119 (2005).

43. *Committee Opinion No. 684: Delayed Umbilical Cord Clamping After Birth*, AM. C. OBSTETRICIANS & GYNECOLOGISTS (Jan. 2017), <https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Delayed-Umbilical-Cord-Clamping-After-Birth?> [<https://perma.cc/CV2Z-TACU>] (recognizing the beneficial effects of delayed cord clamping in the majority of births and recommending a delay of at least thirty to sixty seconds after birth).

1. Spirituality

The placenta has long held spiritual meaning cross-culturally, particularly in the form of ceremonial burial.⁴⁴ Each community has its own beliefs and traditions associated with the placenta, but a common thread is the idea that the proper care and disposal of the placenta and umbilical cord of newborns will affect their and their families' health and well-being. The placenta must therefore be placed or buried in a special spot—be it at or under the parental house, at one of the parents' childhood homes, or under a tree, often with the idea that it will keep the child connected to their home.⁴⁵ Traditionally, Native Hawaiians plant the placenta ('iewe) in the earth following a religious ritual to establish a connection between the mother, child, people, and place.⁴⁶ Native Americans⁴⁷ such as the Navajos bury the placenta so as to return it to Mother Earth.⁴⁸ The Chamorros of Guam have traditional placental burial practices, which Christine Taitano DeLisle argues have represented a form of "indigenous feminism" deployed against U.S. naval colonialism.⁴⁹ These various traditions have inspired Americans from all cultural, ethnic, and racial backgrounds to plant their placentas, often with a tree that grows along with their children, commemorating their birth.⁵⁰

2. Placentophagy and Other DIY Uses

Though almost all mammals consume their placentas, the practice is not common in humans.⁵¹ Some humans do eat their placentas, a practice anthropologists call "maternal placentophagy." The first documented accounts of postpartum women practicing placentophagy were in North America in the

44. Sharon M. Young & Daniel C. Benyshek, *In Search of Human Placentophagy: A Cross-Cultural Survey of Human Placenta Consumption, Disposal Practices, and Cultural Beliefs*, 49 *ECOLOGY FOOD & NUTRITION* 467, 473 (2010).

45. See Young & Benyshek, *supra* note 44, at 482 (reporting on a survey regarding the consumption, treatment, and disposal of placentas in 179 societies).

46. See MacKenzie, *supra* note 16, at 149-50; see also MARY KAWENA PUKUI, *HAWAIIAN BELIEFS AND CUSTOMS DURING BIRTH, INFANCY, AND CHILDHOOD* (2011).

47. See, e.g., William M. Birdsong, *The Placenta and Cultural Values*, 168 *W. J. MED.* 190, 190 (1998) (reporting the case of a Native American woman requesting her placenta be returned for ceremonial disposition in California but failing to indicate her tribal membership).

48. See Lamphere, *supra* note 7, at 1141.

49. Christine Taitano DeLisle, *A History of Chamorro Nurse-Midwives in Guam and a 'Placental Politics' for Indigenous Feminism*, *INTERSECTIONS: GENDER & SEXUALITY ASIA & PACIFIC*, Mar. 2015.

50. Lisa Milbrand, *Planting Your Placenta*, *PARENTS* (2013), <https://www.parents.com/pregnancy/my-body/pregnancy-health/planting-your-placenta> [<https://perma.cc/4H4H-4FWG>].

51. Young & Benyshek, *supra* note 44, at 467.

1970s.⁵² But there is a long history of using the placenta in folk and traditional medicine on other continents. French historian Jacques Gélis reports:

Placentophagy, the custom of eating the newly expelled placenta, has existed at various times amongst people of very different cultures. From the sixteenth century onwards, European travellers to the new world were much struck by this custom, which they unfailingly reported In Europe, however, doctors and churchmen were more and more repelled, from the end of the seventeenth century onwards, by this custom of placentophagy, so 'repugnant to humanity'.⁵³

In other words, when placentophagy became degraded in the colonizers' eyes by its association with the colonized, it fell out of fashion. The downgrading of placentophagy may also have been connected to the demise of the traditional midwifery model controlled by women in favor of the medicalization of birth at the hands of male doctors.⁵⁴

In the United States, placentophagy has become more widely practiced since the mid-2000s. In 2005, natural health enthusiast Jodi Selander began to build an "afterbirth empire. She coined the term *placenta encapsulation* and standardized the method of transforming afterbirth into pills. In 2006, she began selling encapsulation kits and instructional pamphlets, which ship worldwide, through her website, placentabenefits.info."⁵⁵ Fascination with the placenta boomed in the media after *New York Magazine* ran a feature story in 2011 titled *The Placenta Cookbook*.⁵⁶ According to nursing-midwifery professor Emily Hart Hayes, "[a]lthough the number of women who consume their placentas is not known, the large number of placenta encapsulation businesses suggests that it is significant."⁵⁷ Less medicalized birth experiences appear conducive to placentophagy. A 2018 study of 23,525 women who planned a home birth or birthing center delivery as opposed to a hospital birth revealed that nearly one third consumed their placenta.⁵⁸

How is the placenta consumed? The placenta can be consumed raw (by swallowing small pieces or blending it with fruits and other ingredients into smoothies), cooked (e.g., placenta stew or steak), or in a processed form (such

52. See Jodi Selander et al., *Human Maternal Placentophagy: A Survey of Self-Reported Motivations and Experiences Associated with Placenta Consumption*, 52 *ECOLOGY FOOD NUTRITION* 93 (2013).

53. JACQUES GÉLIS, *HISTORY OF CHILDBIRTH* 170 (1996).

54. See generally JEAN DONNISON, *MIDWIVES AND MEDICAL MEN: A HISTORY OF THE STRUGGLE FOR THE CONTROL OF CHILDBIRTH* (1988) (recounting the history of this transition in Europe).

55. Atossa Araxia Abrahamian, *The Placenta Cookbook*, N.Y. MAG. (Aug. 18, 2011), <https://nymag.com/news/features/placenta-2011-8> [<https://perma.cc/66SA-Z7P9>].

56. *Id.*

57. Emily Hart Hayes, *Consumption of the Placenta in the Postpartum Period*, 45 J. OBSTETRIC, GYNECOLOGIC & NEONATAL NURSING 78, 80 (2016).

58. Daniel C. Benyshek et al., *Placentophagy Among Women Planning Community Births in the United States: Frequency, Rationale, and Associated Neonatal Outcomes*, 45 BIRTH 459, 464 (2018).

as capsules and tinctures, as well as preparations for external use such as salves, body butters, oils, and ointments).⁵⁹ Cressida Heyes recounts her own experience of eating her placenta after childbirth:

I was ready for the dinner my partner cooked: whole wheat spaghetti tossed in butter and served with placenta bolognese. It was the best meal I have ever had. What does placenta taste like? As you would expect, it is halfway between muscle and organ, a bit like mince and a bit like liver. There is nothing remarkable about it, especially cooked in a nice sauce. I could have served you my placenta for your dinner and you would never have known the difference.⁶⁰

Encapsulation is a popular method of consumption for those wishing to consume their placenta over a stretch of time or disinclined to eat it in meat form. It involves dehydrating raw or steamed placenta and grinding it into a powder which is encapsulated. According to Jodi Selander and her co-authors, less than 15% of the women surveyed online in 2010 ate their placentas raw while 70% to 80% consumed it encapsulated—and some probably combined the two.⁶¹ Most women hire preparers to encapsulate their placentas for them. In 2007, Selander launched a program designed to train specialists in the process of placenta encapsulation through her Placenta Benefits organization in response to increasing demand for skillful providers.⁶²

Why do people eat their placentas? Advocates of placentophagy suggest that it offers a wide array of postpartum benefits, including hormonal balancing, pain relief, nutrition (such as iron supplementation), improved lactation, more energy, and prevention of postpartum depression.⁶³ Much as traditional placenta rituals have been hypothesized to operate as an anxiety-release mechanism at a time of intense concern for the well-being of new parents and babies,⁶⁴ present-day placentophagy can be analyzed as a coping mechanism for postpartum parents often expected to perform intensive forms of motherhood yet lacking the support they need. Charlotte Kroløkke has argued that new mothers are terrified that they will be physically and emotionally unable to provide the type of care for their newborns and other family members for which they hold themselves responsible, including exclusive breastfeeding, attachment parenting, and other time-intensive and demanding forms of child-rearing.⁶⁵ Placentophagy promises the hope that by popping a pill they will have the ability to live up to these standards.

59. See Hayes, *supra* note 57, at 81; see also Selander et al., *supra* note 52, at 103–04.

60. Heyes, *supra* note 32, at 113.

61. See Selander et al., *supra* note 52.

62. *Id.* at 103.

63. See, e.g., Hayes, *supra* note 57, at 78.

64. See J.R. Davidson, *The Shadow of Life: Psychosocial Explanations for Placenta Rituals*, 9 CULTURE, MED. & PSYCHIATRY 75, 75 (1985).

65. See KROLØKKE, *supra* note 30, at 122–23.

Tellingly, recent empirical work suggests that women who have experienced anxiety or depression prior to pregnancy are more likely to engage in placentophagy in the hope of warding off postpartum depression.⁶⁶

What are the risks and benefits of placentophagy? No serious adverse effects from consuming placentas have been positively established, but clinicians and public health professionals warn of a range of potential risks related to pathogen transmission such as viruses, toxins (heavy metals), and high concentrations of hormones such as estrogen.⁶⁷ The placenta, after all, is (human) meat, which can transmit harmful bacteria and blood-borne diseases such as HIV or hepatitis when consumed raw or undercooked. In 2017 the Centers for Disease Control and Prevention (CDC) issued a report from the Oregon Health Authority announcing that a newborn had contracted late-onset Group B *Streptococcus* disease, one of the most common causes of life-threatening infections in newborns, due to his mother's consumption of her encapsulated placenta.⁶⁸ This case was intensely debated in the placentophagy literature and community as some observers questioned the causality posited by the CDC or suggested that the placenta had not been properly cooked and dehydrated in this case.⁶⁹ In a 2018 study based on a medical records dataset of 23,525, one third of whom had consumed their placentas, no adverse neonatal outcomes were found for babies whose mothers consumed their placenta, whether cooked or uncooked.⁷⁰ The placenta as human meat may even be safer than animal meat, at least to its own producer. As an obstetrician-gynecologist (OBGYN) with whom I talked for this Article underlined, "It's your own placenta so presumably anything that's there you already had."⁷¹

The purported benefits of placenta consumption have been attributed to mineral, vitamin, and hormonal replenishment, but they are still to be substantiated in clinical studies. In 2017, three medical researchers scrutinized the nutritional content of placentas, suggesting a nutrition facts label for it—234

66. Benyshek et al., *supra* note 58, at 466.

67. See, e.g., Hayes, *supra* note 57, at 83-85; see also David Issacs, *Perplexing Perinatal Practices*, 54 J. PAEDIATRICS & CHILD HEALTH 113 (2018). Other risks include the possibility that placentophagy will trigger alloimmunization in women and therefore cause problems in future pregnancies. See Alex Farr et al., *Human Placentophagy: A Review*, 218 AM. J. OBSTETRICS & GYNECOLOGY 401, 403 (2018).

68. Genevieve L. Buser et al., *Notes from the Field: Late-Onset Infant Group B Streptococcus Infection Associated with Maternal Consumption of Capsules Containing Dehydrated Placenta—Oregon, 2016*, 66 MORBIDITY & MORTALITY WKLY. REP. 677 (2017).

69. See, e.g., Jodi Selander, *Can I Get Group B Strep from Placenta Capsules?*, PLACENTABENEFITS.INFO (June 29, 2017), <https://placentabenefits.info/group-b-strep-from-placenta-capsules> [<https://perma.cc/5FZD-BM5Y>] (noting that the placenta was not cooked before it was dehydrated and that the dehydration temperature had been too low to reduce the bacteria present in the tissue).

70. Benyshek et al., *supra* note 58.

71. Interview with OBGYN (Nov. 6, 2018) (the source requested to remain anonymous).

calories for the serving size of an average placenta of 450 grams.⁷² They noted that the “[p]lacenta has significantly less protein than both ground beef and chicken (48 g vs. 77 g and 78 g, respectively), but more iron than both ground beef, ground chicken, and spinach.”⁷³ A few studies about the beneficial effects of placentophagy on lactation were conducted in the 1910s and 1950s,⁷⁴ but have since been discredited due to their flawed research design. A 2015 review concluded that the existing data did not support the claims that placentophagy “helps to enhance lactation, reduce pain, facilitate uterine contraction, or replenish hormones . . . associated with postpartum recovery.”⁷⁵ The same review noted that some of the positive reports on placenta consumption could result from “placebo effects, which could be addressed through a randomized placebo-controlled clinical trial.”⁷⁶ Since this review article, new studies have been released on the mineral⁷⁷ and hormonal⁷⁸ content of placentas. Results of the first randomized, double-blind, placebo-controlled trials evaluating the effects of placentophagy on maternal salivary hormones,⁷⁹ iron status,⁸⁰ and mood, bonding, and fatigue⁸¹ were published in 2017. They uncovered few, if any definite benefits, such as improved postpartum iron status or mood for people who consumed their placentas, compared to those who ingested a placebo. So far, the evidence for positive effects of placentophagy in humans

72. Sydney Chang, Laura Lodico & Zev Williams, *Nutritional Composition and Heavy Metal Content of the Human Placenta*, 60 PLACENTA 100, 101 (2017).

73. *Id.*

74. Frederick S. Hammett & Lyle G. McNeile, *Concerning the Effect of Ingested Placenta on the Growth-Promoting Properties of Human Milk*, 46 SCIENCE 345 (1917); Frederick S. Hammett & Lyle G. McNeile, *The Effect of the Ingestion of Desiccated Placenta on the Variations in the Composition of Human Milk During the First Eleven Days After Parturition*, 30 J. BIOLOGICAL CHEMISTRY 145 (1917); Eva Soyková-Pachnerová et al., *Placenta as a Lactagon*, 138 GYNAECOLOGIA 617 (1954).

75. Cynthia W. Coyle et al., *Placentophagy: Therapeutic Miracle or Myth?*, 18 ARCHIVES WOMEN'S MENTAL HEALTH 673, 678 (2015) (reviewing ten articles, including four on humans and six on animals).

76. *Id.* at 678.

77. Sharon M. Young et al., *Human Placenta Processed for Encapsulation Contains Modest Concentrations of 14 Trace Minerals and Elements*, 36 NUTRITION RES. 872 (2016); see also Chang, Lodico & Williams, *supra* note 72, at 101 (noting that “[d]espite reports of placentas containing harmful levels of heavy metals, there was no arsenic, cadmium, lead, or mercury detected within our pooled placenta sample”).

78. Sharon M. Young et al., *Presence and Concentration of 17 Hormones in Human Placenta Processed for Encapsulation and Consumption*, 43 PLACENTA 86 (2016).

79. Sharon M. Young et al., *Effects of Placentophagy on Maternal Salivary Hormones: A Pilot Trial, Part I*, 31 WOMEN & BIRTH e245 (2017).

80. Laura K. Gryder et al., *Effects of Human Maternal Placentophagy on Maternal Postpartum Iron Status: A Randomized, Double-Blind, Placebo-Controlled Pilot Study*, 62 J. MIDWIFERY & WOMEN'S HEALTH 68 (2017).

81. Sharon M. Young et al., *Placentophagy's Effects on Mood, Bonding, and Fatigue: A Pilot Trial, Part 2*, 31 WOMEN & BIRTH e258 (2017).

remains limited to self-reported surveys,⁸² but future trials may shed further light on the risks and benefits of the practice.

Who eats their placentas? The existing literature suggests that placentophagy is most common among privileged white women. In 2013, Jodi Selander and others conducted a web survey of 189 women in Canada and the United States who self-reported consuming their placentas.⁸³ Survey participants were primarily educated, married (90%), middle-class white women (93%; $N = 189$), 58% of which had a family income above \$50,000/year.⁸⁴ A 2014–2015 study conducted in the Midwest confirmed “that sociodemographic factors play a role in patients’ familiarity with and attitudes toward placentophagy. Participants with higher household income (>\$100,000) and a bachelor’s degree or higher showed a greater willingness to try placentophagy.”⁸⁵ The authors explained these findings by pointing out that individuals with higher socioeconomic status and education are more likely to have access to and to try integrative medical treatment, which are often accompanied by increased out-of-pocket expenses that are not covered by health insurance.⁸⁶ These different studies on the demographics of placenta eaters come to similar conclusions, but it would be worth considering whether the methods used to recruit participants account for some of the findings. The question remains whether the social media groups, online message boards, clinics, and providers used to solicit participation were frequented by diverse groups of parents or whether they were tilted toward white, middle-class women.

Other DIY Uses. Placentas are increasingly employed as an alternative birth phenomenon and to make art. Some parents opt for what is known as a lotus birth, that is, a birth in which the baby is left connected to the placenta until the umbilical cord falls off naturally, which can take up to ten days.⁸⁷ The prolonged contact is seen as a time of transition allowing baby and birthing parent to slowly separate. Other families view placenta arts and crafts as a way of memorializing

82. See Farr et al., *supra* note 67, at 404 tbl.1 (summarizing existing studies on the alleged benefits of placentophagy).

83. See Selander et al., *supra* note 52, at 100. Selander also discusses placenta consumption by people other than the person who grew it, that is, “nonmaternal placentophagia.” *Id.* at 96.

84. See *id.* at 100.

85. Stephanie A. Schuette et al., *Perspectives from Patients and Healthcare Providers on the Practice of Maternal Placentophagy*, 23 J. ALTERNATIVE & COMPLEMENTARY MED. 60, 64 (2017); see also Sharon M. Young et al., *supra* note 79, at 4 (noting that in their sample of twenty-seven Nevadan women who decided to consume their placenta, “[p]articipants were primarily Caucasian ($n = 22$; 81.5%), college educated ($n = 15$; 55.6%), with an average annual household income over \$50,000 ($n = 16$; 59.3%)”).

86. Schuette et al., *supra* note 85, at 64.

87. See Laura A. Zinsser, *Lotus Birth, a Holistic Approach on Physiological Cord Clamping*, 31 WOMEN & BIRTH e73 (2018) (noting that the practice was first reported in humans in 1974 with the case of Californian Clair Lotus Day, who wanted to emulate a chimpanzee practice).

and honoring their child's birth.⁸⁸ Placenta photography documents the placenta, showing it from various angles, or still attached to the baby.⁸⁹ Placenta prints can be made by placing the placenta and the umbilical cord on acid-free paper with the resulting image often resembling a tree, making visually apparent why the placenta is sometimes likened to a tree of life.⁹⁰ Placenta keepsakes can be made with dehydrated umbilical cord shaped into hearts or other symbols. The placental membrane can also be used to make art⁹¹ and powdered placenta turns into a component for custom-made jewelry.⁹² Placenta encapsulators often acquaint their clients with placenta art and offer to produce it as part of their services or for an additional fee.

3. Private Banking

Private placenta banking is the relatively new option to pay a bank to save placental tissue for potential future use, either for the donor's own therapeutic use or for use by other family members.⁹³ Placental tissue has gained a new status as a potential source of multipotent stem cells used to treat a number of diseases.⁹⁴ Private banks that also bank tissues such as cord blood have begun to market their services to expectant parents by emphasizing the promises of regenerative medicine for themselves and their families.⁹⁵ These services operate on the expectation that placental stem cells, once collected, may be regenerated to grow into different types of tissues which will be available for new

88. Melissa Locker, *A New Trend for Parents: Placenta Art Prints*, TIME (Sept. 27, 2013), <https://newsfeed.time.com/2013/09/27/a-new-trend-for-parents-placenta-art-prints> [<https://perma.cc/U7B2-X8XT>].

89. See, e.g., Amy Packham, *Birth Photographer Wants to Show Placentas are 'Unique and Beautiful' in Fascinating Photo Series*, HUFFINGTON POST U.K. (Mar. 13, 2016, 1:03 PM BST), https://www.huffingtonpost.co.uk/entry/placenta-photos-birth-photography_uk_56fd006ae4b069ef5bffe2f6 [<https://perma.cc/4QG7-AWSV>]; Genevieve Shaw Brown, *Placenta Photos Latest Trend in Birth Photography*, ABC NEWS (June 8, 2016), <https://abcnews.go.com/Lifestyle/placenta-photos-latest-trend-birth-photography/story?id=39701285> [<https://perma.cc/X53Z-TLCJ>].

90. Locker, *supra* note 88.

91. *Honoring the Placenta Through Art: Placenta Prints and Cord Keepsakes*, TREE LIFE PLACENTA SERV., <https://www.portlandplacentaservices.com/placenta-prints--keepsakes.html> [<https://perma.cc/8SQC-4J5C>].

92. See, e.g., Anneli Knight, *The Woman Making Jewellery from Placentas*, SYDNEY MORNING HERALD (Aug. 6, 2014, 1:23 PM), <https://www.smh.com.au/business/small-business/the-woman-making-jewellery-from-placentas-20140716-3c0q1.html> [<https://perma.cc/FM6B-5K9N>].

93. See Eleni Antoniadou & Anna L. David, *Placental Stem Cells*, 31 BEST PRAC. & RES. CLINICAL OBSTETRICS & GYNAECOLOGY 13, 24 (2016) (noting that Celgene Cellular Therapeutics was the first company to introduce placental stem cell biobanking in 2012).

94. But see Caroline Chen, *The Birth-Tissue Profiteers*, NEW YORKER (May 7, 2019) (journalistic exposé critiquing the stem cell industry's use of placenta, arguing that placentas are not a source of viable stem cells for treatment and an even poorer source of multipotent stem cells).

95. See KROLØKKE, *supra* note 30, at 130.

personalized therapies in the future. Like cord-blood banking,⁹⁶ placenta banking is future-oriented property that serves as a form of biological insurance, ensuring access to stem cells if a medical need arises. But there are no guarantees that the cells will be usable or that these potential future applications will come to fruition and obtain approval from the United States Food and Drug Administration (FDA) and other agencies.

Private bank Americord currently offers a package for placenta-tissue banking for \$3,499.⁹⁷ Given the hefty price tag, private placenta banking is primarily available to affluent families. In addition to overcoming the significant cost, potential purchasers need to be informed of the option. To solicit customers, most banking services distribute marketing materials in clinical spaces such as private OBGYN and midwives' waiting rooms or prenatal classes. Banking also requires work, as Jennie Haw pointed out in the context of umbilical-cord banking.⁹⁸ Expecting parents must have the time and ability to research organizations offering placenta banking, compare prices and services, attend information sessions, talk to representatives, and coordinate the various institutional and technical processes required to collect the placenta successfully—such as bringing a collection kit with them to the delivery room, ensuring that the placenta is immediately refrigerated, and calling a medical courier promptly for retrieval. Despite the uncertain outcomes, high price tag, and added labor, placenta banks offer to preserve the placenta as an ostensibly valuable future asset.

In brief, the rise of placentophagy, placenta banking, and other personal uses of placentas has endowed them with a new meaning for the mainstream American public—away from waste and toward a private, personal good. But the self-consumption of placentas by birthing parents and their families remains relatively rare. Instead, consumption primarily occurs in conjunction with the use of placentas by third parties. Like other body parts such as organs, tissues, gametes, and blood, placental tissue is fragmented for research and biomedical uses, becoming a scientific resource and public good.

B. Third-Party Uses

This section presents various uses for which third parties collect placentas from healthcare facilities—mainly research, medicine, and cosmetics—before exploring how the placenta supply and demand chain functions.

96. See CATHERINE WALDBY & ROBERT MITCHELL, *TISSUE ECONOMIES: BLOOD, ORGANS, AND CELL LINES IN LATE CAPITALISM* 126 (2006).

97. *Multi-Product Discounts*, AMERICORD, <https://www.americordblood.com/sign-up> [<https://perma.cc/N4GY-E7KR>].

98. Jennie Haw, *Corporeal Commodification and Women's Work: Feminist Analysis of Private Umbilical Cord Blood Banking*, 22 *BODY & SOC'Y* 33 (2016).

1. Research

The scientific study of placentas and their biochemical and physiological properties can be traced back to the end of the nineteenth century. In past decades, the field of placenta research developed rapidly as new applications for placental tissue were uncovered. As sociologist of science Rebecca Yoshizawa explains:

Because they are large, fresh, and widely available tissues, delivered placentas proffer many opportunities to study human physiology and pathology and are uniquely suited to aid in the advancement of human health and well-being through therapeutic applications. As such, tissues and cells from human placentas are regularly collected in hospitals around the world and used in scientific research in diverse fields including reproductive biology, immunology, cancer research, and tissue engineering.⁹⁹

Depending on the type of research and protocol, researchers select placentas of different developmental stages.¹⁰⁰ Full-term placentas (delivered following a full-term pregnancy, which lasts thirty-seven to forty-two weeks) are particularly valuable to study transplacental transfers—that is, whether certain drugs or other substances to which pregnant people are exposed can cross the placental “barrier” and affect the fetus.¹⁰¹ Placentas of various gestational ages are key to understanding pregnancy and its complications, as evidenced by the various biobanks and repositories that not only collect placentas, but also study the functioning of the placenta during pregnancies using MRI scans and other techniques.¹⁰²

Full-term placentas are also used to investigate cohort health, as in the British Avon Longitudinal Study of Parents and Children, which recruited pregnant women from 1990 to 1992, collecting 8,933 placentas and storing them

99. Yoshizawa et al., *supra* note 15.

100. See, e.g., L.M. Wolfe et al., *Banking Placental Tissue: An Optimized Collection Procedure for Genome-Wide Analysis of Nucleic Acids*, 35 *PLACENTA* 645, 646 (2014).

101. See, e.g., Judith A. Smith et. al., *Utilization of an Ex Vivo Human Placental Perfusion Model to Predict Potential Fetal Exposure to Carboplatin During Pregnancy*, 210 *AM. J. OBSTETRIC GYNECOLOGY* 275.e1 (2014) (using ex vivo term placentas collected after delivery to determine whether carboplatin, a common anticancer drug used during pregnancy, crosses the placental barrier).

102. See, e.g., Ctr. for Women’s Health, *Placenta Repository*, OR. HEALTH & SCI. U., <https://www.ohsu.edu/womens-health/placenta-repository> [<https://perma.cc/9EZ8-7LPY>]; see also *About Bioservices*, GLOBAL ALLIANCE TO PREVENT PREMATURITY & STILLBIRTH, <https://www.gapps.org/Home/AboutBioservices> [<https://perma.cc/R3T7-5VZ6>] (describing the mission of the biobank, which includes collecting placentas as a means of fulfilling the “urgent need for biological specimens to support research on complications in pregnancy”). Yale is another example, with its Reproductive and Placental Research Unit, which offers a range of innovative research and testing on the placenta. See *Welcome to the Reproductive and Placental Research Unit*, YALE SCH. MED., <https://medicine.yale.edu/obgyn/kliman> [<https://perma.cc/QX63-N46C>].

in formalin.¹⁰³ The study was designed to determine how biological, environmental, social, genetic, psychological and psychosocial factors impact individuals' survival and health.¹⁰⁴ Geographer Maria Fannin and sociologist Julie Kent argue that the study's researchers viewed the placenta as "an 'archive' of potential information about the future health of the child."¹⁰⁵ In practice, though, the collection was hardly studied by scientists, in part because the method of preservation, formalin, limited research questions.¹⁰⁶

Stem-cell research also relies heavily on placental tissues.¹⁰⁷ First-trimester placentas may be advantageous for this type of research as they are less differentiated than term placentas.¹⁰⁸ Stem cells obtained from first trimester placentas are also offered as a more "ethical" alternative to stem cells harvested from embryos, which are controversial because embryos are destroyed in the harvesting process.¹⁰⁹ The most vocal opposition to the use of embryonic stem cells is premised on the view that embryos should have the same legal and moral status as fully developed humans.¹¹⁰ The law partly reflects this position, as federal law, as well as a number of state laws, restricts the conditions under which fetal tissue can be used for research.¹¹¹ By contrast, the placenta, being a temporary organ, is generally not thought to deserve any special level of consideration. Accordingly, the popularity of placentas as a source of stem cells is such that in 2007, legislative attempts were made to create a regulated national placental stem cell bank under the Stem Cell Research Enhancement Act of 2007.¹¹² The bill was vetoed by President Bush, but it would have established a network of banks to store amniotic fluids and placental cells to maintain a

103. Maria Fannin & Julie Kent, *Origin Stories from a Regional Placenta Tissue Collection*, 34 NEW GENETICS & SOC'Y 25, 30 (2015).

104. *Id.* at 27.

105. *Id.* at 34.

106. *Id.* at 42.

107. Marco Evangelista, Maddalena Soncini & Ornella Parolini, *Placenta-Derived Stem Cells: New Hope for Cell Therapy?*, 58 CYTOTECH. 33 (2008).

108. Saeyoung Park et al., *Comparison of Human First and Third Trimester Placental Mesenchymal Stem Cell*, 37 CELL BIOLOGY INT'L 242, 243 (2013) (comparing stem cells obtained from first- and third-trimester placentas and noting that the former were obtained following miscarriages and the latter following full-term deliveries).

109. See, e.g., Antoniadou & David, *supra* note 93, at 14 ("Fetal stem cells are an alternative plentiful source, and the placenta is now recognized as a rich source of multipotent stem cells.").

110. See Joanna K. Sax, *The Separation of Politics and Science*, 7 STAN. J.L. SCI. & POL'Y 1, 16 (2014).

111. See Gimbel, *supra* note 40.

112. Stem Cell Research Enhancement Act of 2007, S. 5, 110th Cong. (2007). The Act would have allowed federal funding for stem cell research using discarded embryos donated from fertility clinics.

national inventory of high-quality specimens for research and treatment of disease.¹¹³

2. Medicine

“The idea of using the placenta in medicine goes back a long way,”¹¹⁴ noted Jacques Gélis, citing examples of placenta therapies in Europe from antiquity until the seventeenth century. The placenta was thought to be effective to treat a variety of ailments, including skin disorders, epilepsy, apoplexy, erectile tumors, insufficient milk production, infertility, and low libido.¹¹⁵ The placenta was also recognized as a traditional medicine in other regions of the world,¹¹⁶ in particular China, where Li Shizen’s sixteenth century herbology treatise *Compendium of Materia Medica*, regarded as the most complete and comprehensive medical book in the history of traditional Chinese medicine, recommended dried human placenta “to increase energy and vitality and for the treatment of impotence, infertility, liver and kidney problems.”¹¹⁷

In the nineteenth century, Europe witnessed “a renewal of interest in the human placenta, whose immunizing and galactogenic properties were then being discovered, or rather, rediscovered.”¹¹⁸ In contemporary medicine, placentas are used in various forms. Whole, term placentas serve training purposes such as allowing residents to improve their surgical skills.¹¹⁹ Placentas are also employed in barely processed form (as placental blood, membrane, or tissue) for tissue repair (especially of non-healing wounds and burns¹²⁰), for ophthalmic

113. Sheryl Gay Stolberg, *Bush Vetoes Measure on Stem Cell Research*, N.Y. TIMES (June 21, 2007), <https://www.nytimes.com/2007/06/21/washington/21stem.html> [<https://perma.cc/BU8S-AD4U>].

114. See GÉLIS, *supra* note 53, at 168.

115. *Id.* at 169-70.

116. See Willam B. Ober, *Notes on Placentophagy*, 55 BULL. N.Y. ACAD. MED. 591 (1979).

117. LI SHIZHEN, COMPENDIUM OF MATERIA MEDICA: BENCAO GANGMU 4182-4186 (Luo Xiwen trans., 2003) (1593).

118. See GÉLIS, *supra* note 53, at 9.

119. Marcelo Magaldi Ribeiro de Oliveira et al., *Learning Brain Aneurysm Microsurgical Skills in a Human Placenta Model: Predictive Validity*, 128 J. NEUROSURGERY 846 (2018).

120. See, e.g., Ji Suk Choi et al., *Full-Thickness Skin Wound Healing Using Human Placenta-Derived Extracellular Matrix Containing Bioactive Molecules*, 19 TISSUE ENGINEERING 329 (2013); Jong Won Hong et al., *The Effect of Human Placenta Extract in a Wound Healing Model*, 65 ANNALS PLASTIC SURGERY 96 (2010) (double-blind mice study concluding that human placental extracts promote wound healing); U. Manuelpillai et al., *Amniotic Membrane and Amniotic Cells: Potential Therapeutic Tools to Combat Tissue Inflammation and Fibrosis?*, 32 PLACENTA S320 (2011); Adrian L. Watson & Graham J. Burton, *A Microscopical Study of Wound Repair in the Human Placenta*, 42 MICROSCOPY RES. & TECH. 351 (1998); see also Martin C. Robson & Thomas J. Krizek, *The Effect of Human Amniotic Membranes on the Bacterial Population of Infected Rat Burns*, 177 ANNALS SURGERY 144 (1973) (discussing the use of placental tissue to heal burns).

use,¹²¹ for skin grafts,¹²² and for the prevention of postoperative adhesions, among others. Wound specialists Donald Fetterolf and Robert Snyder reported that placental membranes have been employed in the treatment of wounds for almost a century for these purposes.¹²³ They are now commercially available via companies marketing fetal membranes and their derivatives.¹²⁴ Additionally, microscopic compounds and cells are extracted from placentas to produce laboratory developed drugs and products. For instance, until the 1990s, enzymes were commonly harvested from placentas to manufacture notoriously expensive drugs¹²⁵ to treat the Gaucher disease.¹²⁶ Albumin was purified from placentas for use in vaccines.¹²⁷ Nowadays, placental extract is still used in experimental and standard therapies to treat chronic liver disease,¹²⁸ menopause,¹²⁹ periodontal

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121. Augusto Azuara-Blanco, C.T. Pillai & Harminder S. Dua, *Amniotic Membrane Transplantation for Ocular Surface Reconstruction*, 83 BRIT. J. OPHTHALMOLOGY 399 (1999) (describing the use of human placenta for restoration of the cornea).
 122. M. Subrahmanyam, *Amniotic Membrane as a Cover for Microskin Grafts*, 48 BRIT. J. PLASTIC SURGERY 477 (1995) (studying the placental membrane in biologic dressing materials for large defect areas in which skin grafts do not suffice).
 123. Donald F. Fetterolf & Robert J. Snyder, *Scientific and Clinical Support for the Use of Dehydrated Amniotic Membrane in Wound Management*, 24 WOUNDS 299, 299 (2012). Note that authors and practitioners may mean different things when they use the expression “membranes” in relation to the placenta, which is often described as having a fetal side (the amnion or amniotic membrane) and a maternal side (the chorion or chorionic membrane). See Benirschke, *supra* note 33, at 200 (noting that the “entire afterbirth is often referred to as to the fetal membranes”).
 124. See Fetterolf & Snyder, *supra* note 123, at 299 (listing examples of placenta-based products and drugs).
 125. See James R. Hagerty, *Dutchman Who Had Trouble Finding Job at Home Became CEO of a U.S. Biotech Pioneer*, WALL ST. J. (May 19, 2017, 10:00 AM ET), <https://www.wsj.com/articles/dutchman-who-had-trouble-finding-job-at-home-became-ceo-of-a-u-s-biotech-pioneer-1495202400> [<https://perma.cc/C53Z-98BS>] (noting that some of the drugs cost patients hundreds of thousands of dollars a year).
 126. See Ernest Beutler, *Enzyme Replacement in Gaucher Disease*, 1 PLOS MED. 118 (2004); see also Wall St. Journal Staff Reporter, *Genzyme Is Approved to Make a New Drug, Posts Quarterly Loss*, WALL ST. J., Oct. 25, 1996, at B6 (reporting on the FDA’s approval of human placenta-based Cerezyme to treat Gaucher disease).
 127. Joaquin Cabrera-Crespo et al., *Albumin Purification from Human Placenta*, 31 BIOTECH. & APPLIED BIOCHEMISTRY 101 (2000); see also *New Polio Virus Discovery Uses Human Instead of Monkey Tissue*, NEW YORK TIMES 1, July 1, 1955, at 19 (reporting on the discovery of a new way of growing polio virus for vaccines using human placental tissues instead of “expensive monkey kidneys”).
 128. Hideto Shimokobe et al., *Human Placental Extract Treatment for Non-Alcoholic Steatohepatitis Non-Responsive to Lifestyle Intervention: A Pilot Study*, 45 HEPATOLOGY RES. 1034 (2015) (finding human placental extract to be a promising treatment for chronic liver disease).
 129. Mi-Hee Kong et al., *Effect of Human Placental Extract on Menopausal Symptoms, Fatigue, and Risk Factors for Cardiovascular Disease in Middle-Aged Korean Women*, 15 MENOPAUSE 296 (2008).

disease,¹³⁰ respiratory infections,¹³¹ skin disorders,¹³² rheumatic arthritis,¹³³ ulcers,¹³⁴ and wounds, among other indications. The mechanisms by which placental extract produces positive outcomes have yet to be fully clarified and are the subject of ongoing research.¹³⁵ Finally, placenta stem cells figure prominently in tissue engineering and regenerative medicine with the expectation that tissue replacements could be made from patients' own cells or cells retrieved from others.¹³⁶ In 2018, the FDA approved a stem-cell-based therapy derived from the human placenta for emergency treatment following a nuclear event.¹³⁷ Several clinical trials involving placenta-derived cells are on their way.¹³⁸

3. Cosmetics

Human placentas have a long history of use in beauty products, Cleopatra and Marie Antoinette being cited as early adopters.¹³⁹ Charlotte Kroløkke writes that in "the 1950s and 1960s, the placenta became an ingredient in mass-marketed cosmetic products to be consumed by bourgeois, European women."¹⁴⁰ In the 1950s, placental extract was also prescribed for "the efficacious treatment

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130. G. Calvarano, F. De Polis, G. Sabatini, *Trattamento con estratto placentare* [Treatment with Placental Extract in Periodontal Disease], 57 DENTAL CADMOS 85 (1989) (It.).
 131. F. Lo Polito, *Sulla azione di un preparato d'estrazione placentare umano usato per la profilassi delle infezioni respiratorie recidivanti* [Action of a Human Placenta Extract Used for Prevention of Recurring Respiratory Infections], 32 MINERVA PEDIATRICA 261 (1980) (It.).
 132. A. Lodi et al., *Terapia locale di psoriasi con estratto placentare* [Local Therapy of Psoriasis with Placental Extract], 121 GIORNALE ITALIANO DI DERMATOLOGIA E VENEREOLOGIA XV-XVII (1986); S.K. Sharma, R.K. Jain & A.K. Sharma, *Topical Human Placental Extract for the Treatment of Vitiligo*, 54 INDIAN J. DERMATOLOGY, VENEROLOGY & LEPROLOGY 199 (1988).
 133. M. Rosenthal, *The Application of an Extract of Human Placenta in the Treatment of Rheumatic Affections*, 4 INT'L J. TISSUE REACTIONS 147 (1982).
 134. Isabelle Mermet et al., *Use of Amniotic Membrane Transplantation in the Treatment of Venous Leg Ulcers*, 15 WOUND REPAIR & REGENERATION 459 (2007).
 135. See, e.g., Hong et al., *supra* note 120, at 96 (noting that "the mechanism by which HPE enhances wound healing has not been clarified").
 136. Antonietta R. Silini et al., *The Long Path of Human Placenta, and Its Derivatives*, in *Regenerative Medicine*, FRONTIERS IN BIOENGINEERING & BIOTECH., Oct. 2015, at 1.
 137. *Human Placenta-Derived Stem Cell Therapy Approved by USA for Emergency Treatment of Radiation Exposure Following a Nuclear Event*, WIDEACADEMY (Apr. 29, 2018), <https://www.wideacademy.co/2018/04/pluristem-fda-usa-plx-r18-human-placenta-derived-stem-cell-therapy-approved-for-emergency-use/> [<https://perma.cc/2EHZ-2UMP>] (reporting that the FDA cleared Israeli company Pluristem Therapeutics's Investigational New Drug Application for its PLX-R18 therapy in the treatment of acute radiation syndrome).
 138. See Antoniadou & David, *supra* note 93, at 21-22 tbl.2.
 139. POWER & SCHULKIN, *supra* note 36.
 140. See KROLØKKE, *supra* note 30, at 123 (citing W.W. Myddleton, *Modern Trends in Cosmetic Formulation*, 11 J. SOC'Y COSM. CHEMISTS 192, 202 (1959)).

of underdeveloped bust,” or breast augmentation.¹⁴¹ As of 1998, placenta in various forms (protein, enzymes, lipids, and extract) was reported in the United States in over a dozen cosmetic formulations such as hair conditioners, shampoos, tonics, douches, face and body care, and moisturizers.¹⁴² Human placenta-based facials could still be arranged until recently.¹⁴³ Placenta-based beauty products purported to offer a range of benefits including skin hydration,¹⁴⁴ hair growth and anti-hair loss,¹⁴⁵ skin whitening, and anti-aging.¹⁴⁶ Though it appears that American cosmetic companies have stopped using human placentas in their formulations, placenta-based cosmetics can be purchased abroad, particularly in countries like Japan where they are very popular, especially in the form of whitening creams.¹⁴⁷

4. Other Uses

Beyond the uses described above, human placentas have other, unconventional uses. For instance, since human cadaver material is not easy to obtain, placentas are employed to train police dogs to locate missing persons or bodies.¹⁴⁸ Even more curious, in Berlin, Germany, Peter Sloterdijk claims that in the 1990s, placentas were “granulated together with stillborn fetuses and employed as combusive agents in garbage incinerators.”¹⁴⁹ In other words, they were treated as hyperbolic waste—waste used to dispose of other waste.

141. Horst Gohlke, *Use of Placenta Extracts in Cosmetics*, 63 AM. PERFUMER & ESSENTIAL OIL REV. 97, 99 (1954).

142. Bindu Nair & Amy R. Elmore, *Final Report on the Safety Assessment of Human Placental Protein, Hydrolyzed Human Placental Protein, Human Placental Enzymes, Human Placental Lipids, Human Umbilical Extract, Placental Protein, Hydrolyzed Placental Protein, Placental Enzymes, Placental Lipids, and Umbilical Extract*, 21 INT’L J. TOXICOLOGY 81, 84-85 tbl.1 (2002).

143. See Kate Spicer, *Extreme Makeover?*, SUNDAY TIMES (Oct. 21, 2012, 1:01 AM), <https://www.thetimes.co.uk/article/extreme-makeover-kjfbqrb00g> [<https://perma.cc/VW23-36X7>] (reporting that a California dermatologist and enthusiast of placental facials sourced human placentas from Russian maternity wards before turning to sheep).

144. See POWER & SCHULKIN *supra* note 36, at 26.

145. Tae-Rin Kwon et al., *Human Placental Extract Exerts Hair Growth-Promoting Effects Through the GSK-3 β Signaling Pathway in Human Dermal Papilla Cells*, 36 INT’L J. MOLECULAR MEDICINE 1088 (2015) (studying the effectiveness of human placental extract on promoting hair growth and finding that it could potentially treat hair loss).

146. G.A. Hauser, *Placental Extract Injections in the Treatment of Loss of Hair in Women*, 4 INT’L J. TISSUE REACTIONS 159 (1982) (noting that placenta-based products have been popular since the 1930s for whitening and anti-aging creams, but also for hair products and treating the loss of hair).

147. See KROLØKKE, *supra* note 30, at 124-27.

148. See Malia Wollan, *How to Train a Cadaver Dog*, N.Y. TIMES (June 19, 2015), <https://www.nytimes.com/2015/06/21/magazine/how-to-train-a-cadaver-dog.html> [<https://perma.cc/9D5L-85C8>] (reporting that in the United States “dog handlers can legally obtain bodily components like human placenta and blood”).

149. PETER SLOTERDIJK, BUBBLES: SPHERES I, at 384 (2011).

At the other extreme, placentas have been used by the medical profession, the insurance industry, and lawyers as valuable evidence in obstetrical malpractice litigation.¹⁵⁰ When a dispute arises between parents and medical providers as to whether a birth defect or another health issue was caused by improper care before and during the delivery or by other, unrelated causes, the placenta, if it has been collected, examined, and stored in the pathology department, stands witness.¹⁵¹ Expert witnesses are summoned to evaluate the placenta—a healthy placenta typically suggesting a higher likelihood of failure or delay in intervention or inappropriate delivery management, while the detection of placental abnormalities could indicate intrauterine conditions likely to have caused or contributed to the adverse outcome in a way that exonerates medical providers. Considering that obstetric malpractice cases can settle or result in jury verdicts in the millions, placentas have become prized tools of defensive medicine. For example, from 1996 to 2003, the “Cascadia Placenta Registry” preemptively collected hundreds of placentas in Oregon, California, and Washington, unbeknownst to birthing parents, in order to protect doctors and hospitals from potential malpractice lawsuits related to difficult births.¹⁵² The Registry quite literally capitalized on the fact that the placenta is increasingly seen as a “witness” of pregnancy that can provide “valuable information on the cause and timing of many adverse events and conditions.”¹⁵³

5. Sourcing

One of the greatest unknowns in the current bioeconomy is how and where third parties obtain placental tissue. Researchers conducting studies on placental tissues and companies marketing placenta-based products provide varying levels of information about the provenance of their tissues. While some research groups such as the Yale Reproductive Sciences Division, which has its own placenta biorepository, emphasize that they only collect consented placentas¹⁵⁴ from their

150. In 2006 and 2013 noted placenta scientist Harvey Kliman filed patent applications for a “library of biological material” whereby samples of placental tissues would be stored to create a placental library “that may be used for a variety of purposes, including reducing the incidence of medical malpractice claims, identification of members such as paternity testing or suspect identification, pharmaceutical development and epidemiological surveys and research.” See Patents, Patents by Inventor Harvey J. Kliman, JUSTIA (Nov. 14, 2013), <https://patents.justia.com/inventor/harvey-j-kliman> [<https://perma.cc/BWG9-XTXQ>].

151. See Kenneth Tou-En Chang, *Examination of the Placenta: Medico-Legal Implications*, 19 SEMINARS FETAL & NEONATAL MED. 279 (2014) (describing the role of placental findings in the adjudication of cases of adverse neonatal outcome).

152. See *Up to 700 Women in West Not Told About Placenta Registry*, INS. J. (Feb. 13, 2006), <https://www.insurancejournal.com/news/west/2006/02/13/65318.htm> [<https://perma.cc/KZ5D-4YHZ>].

153. See Rebecca N. Baergen, *The Placenta as Witness*, 34 CLIN. IN PERINATOLOGY 393, 394 (2007).

154. See *Yale University Reproductive Sciences Biobank*, *supra* note 102 (noting that they ensure that their biospecimens are “properly consented” and protect “participant safety and privacy”).

affiliated Labor and Delivery units,¹⁵⁵ other researchers or institutions are not as forthcoming.¹⁵⁶ For example, one scientist describes the preparation of human placental extract as follows: “[t]he organs are taken out according to a strict cold chain and frozen at once.”¹⁵⁷ One is left to wonder: Who were the people donating? Were they asked for their consent? If so, when were they approached? By whom? What was the quality of the informed consent? What information was provided to them? Was there any formal agreement or relationship between the healthcare facility treating donors and the organization obtaining placental tissue? These questions often remain unanswered in the literature. In the best case scenario, researchers or placenta product companies mention the name of the hospital from which their placentas are collected or indicate whether informed consent was secured from participants.¹⁵⁸ For example, Judith Smith and colleagues report that, for their study on the transplacental transfer of an anticancer drug from the pregnant woman to the fetus,¹⁵⁹ they obtained placentas “immediately after delivery from either cesarean or vaginal deliveries in accordance with the University of Texas Health Science Center at Houston Medical School Institutional Review Board for Human Studies between August 2009 and May 2011. The Institutional Review Board Committee granted a waiver for obtaining an informed consent for the use of discarded tissues in these studies.”¹⁶⁰

Based on the information available, there seem to be three main sources for placental tissue: 1) leftover tissue from the prenatal test chorionic villus sampling, which is performed around 11 weeks of gestation,¹⁶¹ 2) placental tissue from a miscarried or aborted fetus retrieved surgically,¹⁶² and 3) term

155. Harvey J. Kliman et al., *Pathway of Maternal Serotonin to the Human Embryo and Fetus*, 159 *ENDOCRINOLOGY* 1609, 1626 (2018).

156. I reached out to a dozen private organizations involved in placenta collection, research, processing, or marketing so as to obtain information on their sourcing and procedures, but my requests were largely ignored or refused. Only two tissue procurement organizations handling placental tissue agreed to talk to me.

157. Jean M. Cotte, *A Contribution to the Study of Some Organ Extracts*, *AM. PERFUMER & AROMATICS*, May 1959, at 60, 61.

158. See, e.g., Method for Collecting Placental Stem Cells, U.S. Patent 7,045,148 B2 (filed Dec. 5, 2001) (issued May 16, 2006) (patent noting “Placenta donors were recruited from expectant mothers that enrolled in private umbilical cord blood banking programs and provided informed consent permitting the use of the exsanguinated placenta following recovery of cord blood for research purposes.”).

159. See Smith et al., *supra* note 101, at 275.e2.

160. *Id.*

161. See, e.g., Antoniadou & David, *supra* note 93, at 14 (“Placental tissue can be obtained at a variety of gestational ages if invasive prenatal diagnosis is undertaken.”).

162. See, e.g., Wolfe et al., *supra* note 100, at 646 (using small fragments of placenta collected from women who underwent abortion procedures). Placental tissues from medical abortions or miscarriages passed at home are usually unusable for research and medicine because of bacterial contamination in both abortions and miscarriages and a high rate of genetic abnormalities in miscarriages. See D. Ware Branch et al., *Suitability of Fetal Tissues from Spontaneous Abortions*

placentas collected after the delivery of a live or stillborn baby. The first is described as first-trimester placentas, the second, as first- or second-trimester placentas, and the third, as third-trimester placentas.¹⁶³ Each source has advantages and disadvantages depending on the intended use—namely, for medical therapy or for research. Therapies in which placental tissue is transplanted into patients require donor screening and testing, which is best conducted without haste before a term delivery. By contrast, such testing is not necessary for most research uses. A downside of term placentas is the unpredictability of delivery, making immediate tissue collection difficult.¹⁶⁴ This is one of the reasons why biotech companies and some researchers appear to favor placentas obtained during scheduled C-sections, the other reason being that this collection procedures ensures aseptic retrieval.¹⁶⁵ In addition, there is evidence that placentas delivered vaginally may be structurally different due to compression during the contractions, impacting the data that can be collected for certain studies.¹⁶⁶

Scientists and other stakeholders may be disinclined to broadcast the sourcing of their placentas because a portion comes from miscarried or aborted fetuses. Rebecca Yoshizawa wrote in 2013 that “[f]irst trimester placentas are of increasing interest in placenta science, samples of which are only practically obtained from elective abortion.”¹⁶⁷ Similarly, a multi-disciplinary group of medical researchers and lawyers reported in 2017 that “induced abortion of apparently normal pregnancies is a source of much of the tissue ultimately used for research.”¹⁶⁸ Researchers may understandably seek to avoid becoming the

and from Ectopic Pregnancies for Transplantation, 273 J. AM. MED. ASS’N 66 (1995) (examining embryos obtained from miscarriages and ectopic pregnancies and finding that only 0.05% of the embryos are suitable for human transplantation therapy).

163. See, e.g., Antoniadou & David, *supra* note 93, at 14; Wolfe et al., *supra* note 100, at 646.

164. Wolfe et al., *supra* note 100, at 646.

165. *Royal Biologics Launches Amnio-Maxx™, a Stem Cell Product Derived from Human Amniotic Placental Tissue*, PR NEWswire (Feb. 6, 2018, 2:06 ET), <https://www.prnewswire.com/news-releases/royal-biologics-launches-amnio-maxx-a-stem-cell-product-derived-from-human-amniotic-placental-tissue-300593566.html> [<https://perma.cc/PZS7-YEGK>] (an announcement by Royal Biologics, a New Jersey-based company, of the launch of a placenta-based product to be used in a variety of surgeries, sports medicine, wound care, trauma, and more, priding itself that “[t]he collection of the donor tissue is performed in an aseptic manner by appropriately licensed tissue establishments. All placentas utilized are from planned C-sections, which help to minimize potential contamination during recovery. In addition, placental donors go through rigorous pre-screening qualification and are tested to confirm they are free from disease.”); see also G.J. Burton et al., *Optimising Sample Collection for Placental Research*, 35 PLACENTA 9, 13 (2014) (discussing timing and contamination considerations in the collection of placentas for research).

166. Burton et al., *supra* note 165, at 10.

167. Yoshizawa, *supra* note 29, at 10.

168. Lynn Borgatta et al., *Applications for Research Concerning Fetal or Placental Tissue and Expected Institutional Review Board Responses*, 12 J. EMPIRICAL RES. ON HUM. RES. ETHICS 150, 150 (2017).

targets of heated criticism considering that fetal tissue donation and research¹⁶⁹ is controversial due to antiabortion politics.¹⁷⁰ Federal law governing fetal tissue research essentially prohibits the purchase or sale of the products of conception.¹⁷¹ Human fetal tissue may only be used for research if donors give their informed consent after they have already decided to end the pregnancy,¹⁷² and it must be collected in accordance with state and local law.¹⁷³ Some states forbid any research with aborted tissue¹⁷⁴ and some Institutional Review Boards (IRBs) refuse to consider research proposals on fetal tissues, delay review of such proposals, or impose other barriers upon them.¹⁷⁵ The issue came to the fore in 2015 after an antiabortion group, the Center for Medical Progress, wrongly accused Planned Parenthood of profiting from a fetal-tissue donation program using undercover video reporting.¹⁷⁶ Most recently, in June 2019, the Trump administration ordered scientists who work at the National Institutes of Health (NIH) to stop using fetal tissues from aborted fetuses in their research, prompting concerns that medical discoveries that could advance new treatments to save lives, in particular among infants, would be impeded.¹⁷⁷

What types of institutional and other arrangements are made between healthcare facilities or donors, on the one hand, and individuals or organizations seeking placentas, on the other hand? At least three types of procurements can be identified in light of the information I garnered. First, placental product companies, especially if they have ample resources, appear to create their own sources of supply by soliciting donations directly from pregnant women and coordinating with obstetric teams for retrieval.¹⁷⁸ Second, researchers affiliated with a medical center may enter into direct agreements with its prenatal care and

169. Fetal tissue or cells from diagnostic procedures of amniocentesis or chorionic villus sampling do not meet the definition of fetal tissue. They also do not appear to have specific statutory restrictions related to tissue research. *See supra* note 40 and accompanying text.

170. R. Alta Charo, *Fetal Tissue Fallout*, 373 NEW ENG. J. MED. 890 (2015) (arguing that we have a duty to use fetal tissue for research and therapy because it benefits everyone).

171. *See* NIH Revitalization Act of 1993, Pub L. No. 103-43, 107 Stat. 122 (1993) (codified at 42 U.S.C. § 289g-1 & g-2).

172. 42 U.S.C. § 289g-1.

173. 45 C.F.R. § 46.206 (“Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.”).

174. *See* Borgatta et al., *supra* note 168, at 155.

175. *Id.* at 150.

176. Denise Grady & Nicholas St. Fleur, *Fetal Tissue from Abortions for Research is Traded in a Gray Zone*, N.Y. TIMES (July 27, 2015), <https://www.nytimes.com/2015/07/28/health/fetal-tissue-from-abortion-for-research-is-traded-in-a-gray-zone.html> [<https://perma.cc/GS4E-TCAU>].

177. *See* Susan Jaffe, *Trump Administration Limits Fetal Tissue Research*, 393 LANCET 2381 (2019).

178. This is the model endorsed by MiMedx and Celularity (a New Jersey startup that recently raised \$250 million in seed capital for placenta-derived therapies).

labor and delivery units to obtain placental samples.¹⁷⁹ Finally, the placenta supply chain operates via intermediary entities such as non-profit or for-profit procurement organizations and biobanks that secure placental tissues from medical centers, store them, and offer them to academic, medical, or other organizations. Examples of go-between entities that collect and distribute placental tissue include the company Advanced Tissue Services¹⁸⁰ and AlloSource, one of the largest non-profit cellular and tissue networks in the country that launched a placental donation program in 2017.¹⁸¹

In all of these situations, donors are uncompensated, even though placental tissue was bought and sold between organizations until recently, and perhaps still is. According to an account dating from the 1980s, “[w]hile most hospitals incinerate placentas along with other biological waste, some hospitals sell them to pharmaceutical or cosmetic companies that extract hormones and proteins for use in manufacturing drugs or beauty products.”¹⁸² In 2006, Michelle Oberman wrote:

[C]onsider the former practice of the University of Michigan hospital, which recognized the value it was deriving from the sale of discarded placentas to downstream users by offering new mothers a minor rebate (twenty dollars) on their hospital bills in exchange for their permission to use the placenta. This practice was discontinued when federal regulations on tissue banking foreclosed the practice of selling tissue.¹⁸³

Some of today’s placental-tissue procurement agreements include payments for the medical entities and biobanks that collect and distribute samples. These contracts have the potential to create a revenue stream that can be put back into operations. These organizations must cover the costs of hiring and training staff, purchasing equipment and supplies, developing IT infrastructure to manage data,

179. See, e.g., Dep’t of Obstetrics & Gynecology, *Placenta and Cord Blood Distribution Policy for the Labor and Delivery (L&D) Unit at the Hospital of the University of Pennsylvania (HUP)*, U. PA. HEALTH SYS. (Aug. 24, 2012), <http://www.obgyn.upenn.edu/res/biospecimen.pdf> [<https://perma.cc/SU2S-Q6NA>].

180. See *Placental Tissues*, ADVANCED TISSUE SERV., <https://advancedtissueservices.com/placenta-and-post-natal-products> [<https://perma.cc/CTT6-MFK5>].

181. See *AlloSource Launches Placental Donation Program*, PR NEWswire (Dec. 20, 2017, 12:18 ET), <https://www.prnewswire.com/news-releases/allosource-launches-placental-donation-program-300574034.html> [<https://perma.cc/UW22-9L7U>].

182. Karen Janszen, “*Meat of Life*”, SCI. DIG., Nov/Dec. 1980, at 78; see also Sandy Rovner, *Birth of a Lotion: The Secret Life of Placentas*, WASH. POST, May 13, 1982, at C1 (noting that at the time the George Washington University Medical Center was paid \$1.50 per placenta by pharmaceutical companies to cover hospital handling costs and that “[b]y the time the placental residue is processed for sale to cosmetic manufacturers its price ranges . . . from \$3,000 to almost \$4,000 a pound”).

183. Michelle Oberman, *When the Truth Is Not Enough: Tissue Donation, Altruism, and the Market*, 55 DEPAUL L. REV. 903, 940 (2006) (referring to the National Organ Transplant Act § 301(a), 42 U.S.C. § 274e(a), which states: “It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.”). Note that the placenta arguably does not meet the federal definition of organs. See *infra* Part II.A.3.i.a.

obtaining donors' consent (when they do), processing, and preserving placentas, *inter alia*.¹⁸⁴ The Pennsylvania Health System's guidelines, for example, specify that investigators may be asked to cover the cost of obtaining placental tissue from them, such as staff, space, and equipment.¹⁸⁵ The State of Texas excludes from its 2018 fetal-tissue disposal regulations "placentas designated for sale and obtained from a licensed hospital or a licensed birthing center,"¹⁸⁶ suggesting that placenta selling may still occur.¹⁸⁷ This language was initially included in a 1990 Texas regulation in order to "allow the sale of placentas"¹⁸⁸ and so as not "to preclude the sale of placentas from certain facilities for acceptable purposes" because "certain types of pathological waste may be useful to medical research programs."¹⁸⁹ Presumably the 1990 regulation was the basis of the 2018 language since other portions of the provisions are also similar.

In summary, though little is known about the supply chain of placentas for third-party use, a variety of different arrangements likely exist. The next Part turns to the laws that currently regulate the placenta in its multiple social lives, including as an object of self-consumption, research, therapy, cosmetic treatment, and waste.

II. INEQUITIES OF PLACENTAL ECONOMIES

There is no single definition of the placenta under federal law. Instead, different uses of the placenta have been regulated separately, including as waste; tissue; research subject; drug; and food, dietary, or cosmetic ingredient. Less than a dozen states have adopted an explicit definition of the placenta, be it to exclude it from the category of fetal tissue¹⁹⁰ or to classify it as an organ,¹⁹¹ a

184. See generally Chris Andry et al., *Biobanking—Budgets and the Role of Pathology Biobanks in Precision Medicine*, 4 ACAD. PATHOLOGY 1 (2017) (discussing the start-up and operational costs of biobanking).

185. Dep't of Obstetrics & Gynecology, *supra* note 179, at 2-3.

186. 25 TEX. ADMIN. CODE § 138.3(c)(1) (2018).

187. 25 TEX. ADMIN. CODE § 1.133(a)(2)(C) (2018) (exempting "placentas designated for sale and obtained from a licensed hospital or a licensed birthing center" from the coverage of certain waste disposal standards).

188. 15 Tex. Reg. 2235 (Apr. 20, 1990).

189. 15 Tex. Reg. 4818 (Aug. 21, 1990).

190. MINN. STAT. § 137.47(c) (2018) ("Fetal tissue" means any body part, organ, or cell of an unborn human child. Fetal tissue does not include tissue or cells obtained from a placenta, umbilical cord, or amniotic fluid."); TEX. HEALTH & SAFETY CODE ANN. § 697.002(3) (2018) ("Embryonic and fetal tissue remains" means an embryo, a fetus, body parts, or organs from a pregnancy that terminates in the death of the embryo or fetus and for which the issuance of a fetal death certificate is not required by state law. The term does not include the umbilical cord, placenta, gestational sac, blood, or body fluids.").

191. ARK. CODE ANN. § 20-8-503(3) (2018) ("Placenta" means the organ that forms on the inner wall of the human uterus during pregnancy"); GA. CODE ANN. § 31-46-2(3) (2018) ("Placenta" means the organ that forms on the inner wall of the human uterus during pregnancy.").

human tissue,¹⁹² a specimen,¹⁹³ a component of the broader notion of product of conception,¹⁹⁴ as medical or pathological waste,¹⁹⁵ or as several of the above depending on the purpose for which the placenta is considered.

This hodgepodge of federal and state laws results in simultaneously granting third parties wide access to placentas while insufficiently protecting individuals' autonomy over their placentas. On the one hand, birthing parents and their families may be prevented from keeping their placenta or making informed decisions about donating it, while, on the other hand, third parties may sometimes procure placental tissue without obtaining the specific and explicit consent of the producers.¹⁹⁶ This asymmetry creates a cycle of dispossession for pregnant people whereby their reproductive and placental labor may be transformed into products and therapies, which are sold on the medical and cosmetic markets. In what follows, I argue that the current legal framework facilitates third-party access to placentas in a way that reinforces the

192. ARK. CODE ANN. § 20-8-503(4) (2018) ("‘Postnatal tissue and fluid’ means the placenta, umbilical cord, and amniotic fluid expelled or extracted in connection with the birth of a human being"); ARK. CODE ANN. § 20-17-801(C) (2018) ("‘Human tissue’ means any tissue of the human body, including without limitation an external member of the human body, placenta, or fetal connective tissue"); GA. CODE ANN. § 31-46-2(4) (2018) ("‘Postnatal tissue and fluid’ means the placenta, umbilical cord, and amniotic fluid expelled or extracted in connection with the birth of a human being.").

193. 28 PA. CODE § 135.15 (2018) ("A hospital may elect not to send the following categories of specimens to the laboratory for pathologic examination . . . (5) Placentas that are grossly normal and have been removed in the course of operative and nonoperative obstetrics.").

194. LA. ADMIN. CODE tit. 48, § 4401 (2018) ("‘Products of Conception—placenta, amniotic sac or membrane, embryo, or fetal elements that result from a human pregnancy.'"); MICH. COMP. LAWS ANN. § 333.13807 (West 2019) ("(5) ‘Products of conception’ means any tissues or fluids, placenta, umbilical cord, or other uterine contents resulting from a pregnancy."); N.M. STAT. ANN. § 24-9A-1(G) (2018). ("‘fetus’ means the product of conception from the time of conception until the expulsion or extraction of the fetus or the opening of the uterine cavity, but shall not include the placenta"). In Arkansas and Mississippi, on the other hand, the placenta is explicitly excluded from the definition of product of conception. See ARK. CODE ANN. § 20-17-801 (b)(2)(A) (West 2019) ("‘Dead fetus’ means a product of human conception exclusive of its placenta"); MISS. CODE ANN. § 41-39-1 (2019) ("a dead foetus is defined as a product of human conception, exclusive of its placenta").

195. GA. COMP. R. & REGS. 391-3-4.15(2)(a) (2018) ("Pathological waste, which means all recognizable human tissues and body parts except teeth which are removed during surgery, obstetrical procedures, autopsy, and laboratory procedures."); HAW. CODE R. § 11-104.1-2 (LexisNexis 2018) ("‘Human pathological waste’ means all tissue, organs (including placenta, tonsils, and gall bladder"); ILL. ADMIN. CODE tit. 77, § 265.2050(a) (2018) (providing that, for birth centers, "[a]ll pathological and bacteriological waste, including blood, body fluids, placentas, sharps and biological indicators, shall be disposed of by a waste hauler"); 28 PA. CODE § 501.84 (2018) ("Disposal of Placenta. Pathological and bacteriological waste, surgical and obstetrical wastes, contaminated wastes, and similar materials shall be incinerated on the premises or disposed of by a method approved by the Department of Environmental Resources and in compliance with local regulations."); 25 TEX. ADMIN. CODE § 1.132(42) (2018) ("Pathological waste . . . includes but is not limited to: (A) human materials removed during surgery, labor and delivery"); 25 TEX. ADMIN. CODE § 137.38(1) (2018) ("All special waste including blood, body fluids, placentas").

196. See *supra* note 9 and accompanying text (noting that patients typically sign blanket consent forms saying that all the data or tissue samples collected as part of their medical care belong to the doctor of the institution providing the care, thus implicitly including the collection of the placentas of pregnant patients who undergo CVS testing, experience D&Cs and D&Es, have surgical abortions, and give birth).

vulnerability of already marginalized groups—pregnant people, especially those who are also low-income or of color.

A. The Law of Third-Party Access to Placentas

Third parties such as researchers, clinicians, biobanks, biotech firms, and cosmetic companies enjoy relatively easy access to placentas, which are often presented as free from ethical quandaries and available for the taking.

1. The Placenta as Waste

Federal law regards bodily parts and fluids collected in healthcare facilities in the course of diagnosis and treatment as medical or pathological waste.¹⁹⁷ No uniform definition exists as to what constitutes medical waste according to state law,¹⁹⁸ but a majority of states define the placentas as medical or pathological waste, be it explicitly¹⁹⁹ or implicitly, as the practical outcome of not defining placentas is that they typically fall under the category of medical or pathological

197. See Elizabeth Kimball Key, *The Forced Choice of Dignified Disposal: Government Mandate of Interment or Cremation of Fetal Remains*, 51 U.C. DAVIS L. REV. 305, 313 (2017) (noting that medical waste is “potentially infectious waste material generated by healthcare facilities, including but not limited to: bloodied bandages, discarded surgical gloves, removed body organs, discarded needles, and cultures of infectious agents. Pathological waste, a subset of medical waste, consists of recognizable human or animal body parts.”); see also Sarah Dry, *Who Owns Diagnostic Tissue Blocks?*, 40 LABORATORY MED. 69, 70 (2009) (noting that under state law tissues collected for diagnostic use and processed into paraffin blocks must typically be kept in medical facilities’ storage for a number of years before they can be discarded).

198. Kimball Key, *supra* note 197, at 312.

199. GA. COMP. R. & REGS. 391-3-4.15(2)(a) (2018) (“Pathological waste, which means all recognizable human tissues and body parts except teeth which are removed during surgery, obstetrical procedures, autopsy, and laboratory procedures.”); HAW. CODE R. § 11-104.1-2 (LexisNexis 2018) (“‘Human pathological waste’ means all tissue, organs (including placenta, tonsils, and gall bladder)”; ILL. ADMIN. CODE tit. 77, § 265.2050(a) (2018) (providing that, for birth centers, “[a]ll pathological and bacteriological waste, including blood, body fluids, placentas, sharps and biological indicators, shall be disposed of by a waste hauler”); MICH. COMP. LAWS § 333.13807 (2018) (“(2) ‘Pathological waste’ means human organs . . . [and] products of conception. . . . (5) ‘Products of conception’ means any tissues or fluids, placenta, umbilical cord, or other uterine contents resulting from a pregnancy.”); 28 PA. CODE § 501.84 (2018) (“Disposal of Placenta. Pathological and bacteriological waste, surgical and obstetrical wastes, contaminated wastes, and similar materials shall be incinerated on the premises or disposed of by a method approved by the Department of Environmental Resources and in compliance with local regulations.”); 25 TEX. ADMIN. CODE § 1.132(42) (2018) (“Pathological waste . . . includes but is not limited to: (A) human materials removed during surgery, labor and delivery”); 25 TEX. ADMIN. CODE § 137.38(1) (2018) (“All special waste including blood, body fluids, placentas”).

waste.²⁰⁰ Many states also incorporate the relevant federal law by reference.²⁰¹ More often than not, medical providers and regulators consider placental tissue to be a waste product described as “discarded,” “residual,” or “leftover” tissue.²⁰²

This classification conforms with both the common law tradition²⁰³ and the Roman law notions of *res nullius* (a thing that belongs to no one) or *res derelictae* (a thing which has been abandoned by its owner). As such, placentas are regulated through medical-waste disposal regulations, in particular the federal Occupational Safety and Health Act (OSHA) and its state counterparts. OSHA defines medical/infectious waste requiring special discard as “[h]uman pathological waste, including tissues, organs, and body parts and body fluids that are removed during surgery or autopsy, or other medical procedures, and specimens of body fluids and their containers.”²⁰⁴ These types of waste must be sequestered from other, not infectious wastes, and burned in federally licensed incinerators.²⁰⁵ To comply with OSHA, all professionals exposed to any infectious materials must take “universal precautions . . . to prevent contact with blood or any other infectious materials.”²⁰⁶

But what is waste? Something that has no use or value and must be disposed of. Categorizing the placenta as waste is convenient. It justifies both denying individuals access to it on the ground that it is infectious and granting third

200. ALA. CODE § 22-27-2 (2018); ARIZ. ADMIN. CODE § 13-200-212 (2018); CAL. HEALTH & SAFETY CODE § 117690 (West 2018); COLO. REV. STAT. § 25-15-402 (2018); DEL. CODE ANN. tit. 7, § 6402 (2018); D.C. CODE § 8-901 (2018); FLA. STAT. § 403.703 (2018); IDAHO CODE § 39-103 (2018); 415 ILL. COMP. STAT. § 5/3.360 (2018); IND. CODE ANN. § 16-41-16-5 (West 2018); IOWA CODE § 455B.501 (2018); KAN. ADMIN. REGS. § 28-19-729a (2018); 401 KY. ADMIN. REGS. 61:013 (2018); 06-096-100 ME. CODE R. § 096-100-178-E (LexisNexis 2018); 105 MASS. CODE REGS. 480.010 (2018); MINN. STAT. § 116.76 (2018); MISS. CODE R. § 15-16-1:52:26 (2018); MO. CODE REGS. ANN. tit. 10, § 80-7.010 (2018); MONT. CODE ANN. § 75-10-1003 (2018); 132 NEB. ADMIN. CODE § 1-053 (2018); NEV. ADMIN. CODE § 444.600 (2018); N.H. REV. STAT. ANN. § 125-M:2 (2018); N.Y. PUB. HEALTH LAW § 1389-aa (McKinney 2018); 15A N.C. ADMIN. CODE 13B.1201 (2018); N.D. ADMIN. CODE 33-20-12-01 (2018); OHIO REV. CODE ANN. § 3734.01 (West 2018); OKLA. ADMIN. CODE § 310:616-5-2 (2018); 23 R.I. GEN. LAWS § 23-19.12-3 (2018); S.D. CODIFIED LAWS § 34A-6-93 (2018); TENN. COMP. R. & REGS. 1200-08-10-.10 (2018); UTAH CODE ANN. § 19-6-102 (West 2018); 16-3 VT. CODE R. § 200 (2018); 9 VA. ADMIN. CODE § 20-120-150 (2018); WASH. REV. CODE § 70.95K.010 (2018); W. VA. CODE § 20-5J-3 (2018); WIS. STAT. § 287.07 (2018); 020-0002 WYO. CODE R. § 4 (2018).

201. 40 C.F.R. § 60.51 (2018).

202. See Yoshizawa, *supra* note 29, at 9, 11.

203. See Jean McHale, *Waste, Ownership and Bodily Products*, 8 HEALTH CARE ANALYSIS 123 (2000) (discussing English laws’ approach to bodily parts as waste).

204. 40 C.F.R. § 60.51c(2) (2018). Taken literally, however, federal regulations of medical waste should in theory only apply to placentas delivered via diagnostic procedures, surgical abortions, D&Cs, and C-sections, not to those obtained after a vaginal delivery. Vaginal birth is a normal physiologic process, not a pathology requiring medical interventions. Nonetheless, all placental tissues extracted or expelled from the body in a healthcare facility appear to be considered medical waste. The placenta could also fall within the “other potentially infectious materials” definitions provided by the statute, which includes “[a]ny unfixed tissue or organ (other than intact skin) from a human (living or dead).” 29 C.F.R. § 1910.1030(b)(1) (2019).

205. *Id.*

206. *Id.* at § 1910.1030(d)(1).

parties access to it on the ground that it is abandoned and will be put to good use.²⁰⁷ This classification has been criticized by others before.²⁰⁸ It poses at least two interrelated problems: 1) it constructs placentas as available and unproblematic by contrast to embryonic or fetal tissues, perpetuating the representation of the female body itself as waste; and 2) it pathologizes people's DIY use of their placentas as hazardous.

i. The Placenta as Available Tissue

According to Rebecca Yoshizawa and her colleagues, “[w]aste is a rhetorical category adjudicating powers to decide the meaning of, and what happens to, alienated bodily flesh in biomedicine.”²⁰⁹ Their study underlines that the waste categorization serves as a rationale for collecting placentas for research or clinical use without obtaining consent.²¹⁰ Under federal research law, when tissues are de-identified, that is, so long as donors' identifiers (such as name, record or social security numbers, date of birth, and so on²¹¹) do not accompany samples, they are typically *not* considered “human subjects.”²¹² According to the Common Rule developed by the U.S. Department of Health and Human Services,²¹³ leftover clinical samples may be used for research when no longer needed for patient care without securing patient consent, as long as the physical sample and any associated data sets cannot be linked to specific, living individuals. In practice, because placentas are treated as discarded tissue by healthcare facilities, they most often meet the requirements for de-identified tissues.²¹⁴ Sociologists investigating pregnant people's *perceptions* of their placentas through individual interviews would be considered as conducting human subjects research. They would likely be required by their institution's Institutional Review Board to obtain participants' informed consent and to take

207. Rachel Ariss, *Theorizing Waste in Abortion and Fetal Ovarian Tissue Use*, 15 CAN. J. WOMEN & L. 255, 256 (2003) (“A recurrent thread supporting ethical discussion in favour of using reproductive materials is found in concepts of waste and wastefulness. It is assumed, rather than argued, that using reproductive materials (such as fetal tissue, frozen embryos, and umbilical cords), which have no other purpose and, therefore, will be wasted, is an inherent ‘good.’”).

208. See, e.g., McHale, *supra* note 203; Yoshizawa, *supra* note 29; see also Charlotte Kroløkke, Elizabeth Dickinson & Karen A Foss, *The Placenta Economy: From Trashed to Treasured Bio-Products*, 25 EUR. J. WOMEN'S STUD. 138, 148-50 (2016).

209. Yoshizawa et al., *supra* note 15, at 77 (citing scientists who reported using placentas without explicit, informed consent because placentas are “considered throwaway tissue”).

210. *Id.*

211. Other participant information may accompany the sample and still be considered “de-identified.” Information that may accompany the sample includes approximate date of collection; certain diagnoses and medical history; and gender, age, race, or ethnic group.

212. 45 CFR § 46.102(e) (2016).

213. See generally 45 C.F.R. §§ 46.101-46.124 (2014).

214. See Div. of Microbiology & Infectious Diseases, *Good Clinical Practice Resource Guide*, U.S. DEP'T HEALTH & HUM. SERV. (Dec. 2015).

steps to protect their confidentiality. By contrast, investigators using actual, de-identified placentas are typically not required to obtain donors' consent given that their activities fall under the category of non-human research.²¹⁵

When discarded placental tissue is sought for clinical or commercial use as opposed to research, healthcare facilities are not bound by Institutional Review Board rules. These facilities' ethical (or other internal) committees have discretion as to whether to donate or sell the tissues, and whether to obtain donors' specific consent. A number of organizations do seek donors' specific consent rather than relying on the blanket consent forms patients sign at the time of admission.²¹⁶ Yet, even when consent is actively sought, the waste paradigm continues to dominate the discourse surrounding placenta donation and research. Celularity, for example, a New Jersey biotech company that uses placenta stem cells to produce therapies to augment immunity and longevity, features on its website a chart depicting the placenta as under-utilized, accompanied by the following formula: "130M births per year globally <.01% of placentas are utilized 1 placenta = 100K+ medical treatments."²¹⁷

When construed as waste, placentas are viewed as available for the taking, both practically and ethically. Practically, collecting them can be as easy as dumpster diving—the perfectly legal activity of foraging through another person's garbage left in the public space to obtain discarded materials.²¹⁸ Ethically, researchers and other stakeholders contend that placentas are free from the controversies²¹⁹ raised by other female reproductive tissues such as eggs, embryos, and fetuses.²²⁰ From a regulatory perspective, the placenta is not considered fetal tissue, and thus is exempt from the federal and state laws governing fetal tissue donation and research.²²¹ Halkoaho notes that the claim

215. See 45 C.F.R. § 46.102(e); see also *Human Subject Regulations Decision Charts*, U.S. DEP'T HEALTH & HUM. SERV. (Feb. 16, 2016), <https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html> [<https://perma.cc/MQV2-3ZTK>] (explaining when research will be considered human subject research under 45 C.F.R. 46).

216. See Petrow, *supra* note 13.

217. CELULARITY, <https://www.celularity.com> [<https://perma.cc/697H-GEEN>].

218. *California v. Greenwood*, 486 U.S. 35 (1988) (holding that there is no reasonable expectation of privacy for garbage that is accessible to members of the public); see also Arielle Zions, *Placenta Taken Without Warrant Will Be Used as Evidence in Rape Case*, RAPID CITY J. (Nov. 16, 2019), https://rapidcityjournal.com/news/local/crime-and-courts/placenta-taken-without-warrant-will-be-used-as-evidence-in/article_f77dc0bc-5686-5e30-984b-40677021df1d.html [<https://perma.cc/6B79-2Z6A>] (reporting that, according to some law enforcement officers and judges, no warrant is necessary to seize placentas from abortion clinics because they are medical waste).

219. Julie Kent, Maria Fannin & Sally Dowling, *Gender Dynamics in the Donation Field: Human Tissue Donation for Research, Therapy and Feeding*, 41 SOC. HEALTH & ILLNESS 567, 575 (2018).

220. See Yoshizawa, *supra* note 29.

221. 42 U.S.C. § 289g-1(g).

that the placenta is waste has even been deployed to advocate for less-strict ethical guidelines for its collection.²²²

Treating placentas as waste also perpetuates the long Western tradition of suspicion and debasement of the female body and its secretions.²²³ Rachel Ariss's discussion of waste tissue highlights how the reproductive labor of women is generally tied to notions of wastefulness, as "reproduction is simply another form of commodity production, and either a new product, or waste, must be the result."²²⁴ Emily Martin's feminist anthropology of science helps explain why female reproductive tissues in particular tend to be seen as waste.²²⁵ For generations, the female reproductive functions have been represented in medical texts as a cycle of degeneration and decay generating waste at every stage—unfertilized eggs, falling away uterine lining, menopause, and so on.²²⁶ The placenta could be added to the list, whether obtained following diagnostic testing, pregnancy termination, loss, or birth. In all of these instances, it is no longer needed to physically nourish and protect valued fetuses, transitioning from essential to support life to useless remnant of a pregnancy.

ii. The Pathologizing of Self-Consumption

Still another persistent problem with the categorization of the placenta as waste is that it pathologizes DIY uses as risky and deviant, while vindicating taking and transforming placenta into processed products in the hands of research, medical, and cosmetic organizations. State statutes and regulations as well as medical centers' internal guidelines construct placentas as dirty, polluting waste, to use notions famously articulated by anthropologist Mary Douglas. Douglas defined "dirt as matter out of place."²²⁷ According to her, in human cultures, dirt must typically be excluded to preserve pattern or sense of order.²²⁸ Framing the placenta as infectious waste to be excluded may be another way of imposing a form of order on childbirth, contributing to its medicalization and prescribing conditions on pregnant and birthing people's engagement with their own body. This waste conception empowers legal and medical institutions to

222. A. Halkoaho, A.-M. Pietilä & K. Vähäkangas, *Ethical Aspects in Placental Perfusion Studies: Views of the Researchers*, 32 *PLACENTA* 511 (2011).

223. See, e.g., Ros Bramwell, *Blood and Milk: Constructions of Female Bodily Fluids in Western Society*, 34 *WOMEN & HEALTH* 85 (2001).

224. Ariss, *supra* note 207, at 264.

225. See generally EMILY MARTIN, *THE WOMAN IN THE BODY: A CULTURAL ANALYSIS OF REPRODUCTION* (2001).

226. See Emily Martin, *The Egg and the Sperm: How Science Has Constructed a Romance Based on Stereotypical Male-Female Roles*, 16 *SIGNS* 485, 489 (1991).

227. MARY DOUGLAS, *PURITY AND DANGER: AN ANALYSIS OF THE CONCEPTS OF POLLUTION AND TABOO* 36 (1984).

228. *Id.* at 41.

regulate individuals' relationship with their own placentas even when allowed to keep them. It justifies restrictive clauses placed on release such as the requirement that producers test negative for a variety of blood-borne illnesses and be educated in safe handling practices, or that the placenta itself be tested for germs. While the health concerns behind these restrictions are real, people who grow placentas should retain greater autonomy in what to do with their own tissue. After all, people of reproductive age routinely handle bodily materials such as menses safely on their own. Should drinking one's own menstrual blood become a trend, it would be difficult to fathom how health authorities could enact and enforce limitations similar to those placed on placenta.²²⁹

When the placenta is not depicted as waste, it is framed as a gift to be expected from selfless feminized donors.

2. *The Placenta as Gift*

In the recruitment of placenta donors, banks and biotech companies rely on gendered stereotypical notions, according to which women are altruistic and motivated by the desire to help others rather than by financial incentives. These assumptions are not specific to placental donation, as gender appears to shape the dynamics of tissue donation generally. Julie Kent, Maria Fannin, and Sally Dowling have argued that "in general, and across comparative country contexts, more women donate organs than men, and more men are recipients of donated organs than women."²³⁰ Physician Naomi Duke notes that some bodies are "forced, trained, and programmed to give."²³¹ Women, particularly women of color, are culturally constructed as selfless and giving, bearing responsibility for the care of their family. Their bodies are seen as without border, especially in relation to pregnancy, which is treated as a public event—from ultrasounds, which bare wombs for all to see, to reproductive decisions, which are often made by parties other than women themselves.

Georgia biopharmaceutical company MiMedx's donation website illustrates this construction of the female body as both wasteful and altruistic. The home page intimates, "Donate your placenta," "Give the gift of healing," "Help dozens

229. "Womb Witch" Urges Women to Drink Their Own Menstrual Blood to Boost Energy Levels, MIRROR (Feb. 12, 2018), <https://www.mirror.co.uk/news/weird-news/womb-witch-urges-women-drink-12015423> [<https://perma.cc/BW6W-LN4X>] (suggesting that the idea of drinking one's own menstrual blood is actively practiced).

230. Kent, Fannin & Dowling, *supra* note 219, at 3.

231. Naomi N. Duke, *Situated Bodies in Medicine and Research: Altruism versus Compelled Sacrifice*, in THE GLOBAL BODY MARKET, *supra* note 23, at 107, 107-109 (critiquing how altruism is often deployed in medicine and research, and in particular denouncing the exploitation of African-Americans as "altruistic bodies").

of patients,” accompanied by pictures of smiling babies.²³² MiMedx’s donation brochure expounds further:

It is vital that you donate. The amniotic membrane (amnion) within the placenta has unique healing properties not found in other tissues. It consists of a special combination of cells with specific functions that aid the healing process. Why let it go to waste? One placenta donation can improve the quality of life for dozens of people.²³³

The website does not indicate that MiMedx is a for-profit company that uses placental tissue to manufacture and market lucrative products, cultivating instead the perception of a charitable organization. The FAQs page includes the following Q&A:

—Will I be given monetary compensation for my donation?

—No. We are extremely appreciative of this act of charity; however, due to federal laws, we cannot provide any monetary compensation.²³⁴

This passage is puzzling considering that the federal government does not classify the placenta as an organ and, therefore, does not make it illegal to compensate donors. It also contradicts a statement, made by a MiMedx spokesman to journalist Matilda Battersby in 2018, that the company has “not taken a position relative to incentivizing donors, but believe[s] it could become an important topic for policy discussion.”²³⁵

The gendering of placental tissue donation is compounded by the fact that it is overwhelmingly men who reap the reputational and economic benefits associated with the research, processing, and selling of ideas and products derived from placentas. The leading biotechnology companies using placentas are run by men. MiMedx, though it has faced a reshuffling of its executives in 2018, counts nine men on its management team for one woman, and eight men for one woman on its Board of Directors.²³⁶ New Jersey company Celularity was

232. PLACENTA DONATION PROGRAM, <https://www.placentadonation.com> [<https://perma.cc/F6SJ-VS89>].

233. Placenta Donation Program, *Give the Gift of Healing*, MiMEDX TISSUE SERV., https://www.placentadonation.com/sites/default/files/Placenta_Donation_Brochure.pdf [<https://perma.cc/UHY9-489F>].

234. *FAQs*, PLACENTA DONATION PROGRAM, <https://www.placentadonation.com/questions> [<https://perma.cc/9ARY-R2UU>].

235. Matilda Battersby, *Should We Pay Mothers to Donate Placentas?*, MEDIUM (July 25, 2018), <https://medium.com/s/story/should-we-pay-mothers-to-donate-placentas-607283042ef1> [<https://perma.cc/RL6B-FZV5>].

236. *Board of Directors*, MiMEDX, <https://mimedx.com/board-of-directors> [<https://perma.cc/K4TB-ZXRN>]; *Management Team*, MiMEDX, <https://mimedx.com/management-team> [<https://perma.cc/6TVT-UB7D>].

founded by two men²³⁷ and its Board of Directors consists exclusively of men.²³⁸ Noveome Biotherapeutics, Inc., a Pennsylvania biotech company founded and headed by a man, counts five men and one woman on its “leadership team”²³⁹ and all of its Directors are men.²⁴⁰ Though this gender disparity is typical of the biotech sector, it strikes as especially problematic when the raw material capitalized upon is produced by female reproductive labor. Placental economies offer a vivid reminder that the age-old paradigmatic sexual division of labor—women reproduce while men produce—is still alive and well.

3. *The Placenta as Product*

Within the complex cycle of placental economies, some individuals may be in the position to become (symbolically at least) customers of their own bodies. Their buying back of their placenta takes several forms, from placenta-based drugs and clinical products that show promise for medical indications ranging from cancer to wound care, to cosmetics such as skin lotions and hair treatments. Some of these products seem to be safe, effective, and much needed for patient care, while others entail serious health risks. In what follows, I review the bifurcated federal regulation of the placenta as a tissue, dietary ingredient, food, and cosmetic ingredient, highlighting the different risk calculus at work under each category.

i. The Placenta as Tissue

The placenta is often referred to as an organ in the scientific literature, but it does not meet the federal definition of organs under the National Organ Transplant Act given that it cannot be used for direct transplantation.²⁴¹ Instead, when used for therapeutic purposes, the placenta is regulated under the Public Health Service Act as a “Human Cell Tissue Product” (HCT/Ps) on the basis that it consists “of human cells or tissues” which may be “intended for implantation, transplantation, infusion, or transfer into a human recipient.”²⁴² The regulation of the placenta as tissue is highly complex. The FDA has developed a three-tier classification system for HCT/Ps based on the degree of risk posed to public

237. Matthew Herper, *Celgene Spinout Celularity Raises \$250 Million to Develop Placental Cells to Attack Cancer*, FORBES (Feb. 15, 2018, 9:00 AM), <https://www.forbes.com/sites/matthewherper/2018/02/15/celgene-spinout-celularity-raises-250-million-to-develop-placental-cells-to-attack-cancer> [https://perma.cc/NQ6R-9WTW].

238. *Board of Directors*, CELULARITY, <https://www.celularity.com> [https://perma.cc/697H-GEEN].

239. *Leadership*, NOVEOME, <https://noveome.com/company/#leadership> [https://perma.cc/R6B5-NXTY].

240. *Id.*

241. National Organ Transplant Act, 42 U.S.C. § 274e(a)(e).

242. 21 C.F.R. § 1271.3(d) (2018).

health and individual recipients.²⁴³ There has been some controversy as to whether certain placental products fall under the second (middle-risk) or the third (high-risk) tier. For companies using placentas, marketing their products as outside the high-risk category presents the enormous advantage of circumventing the lengthy and expensive regulatory process applied to high-risk HCT/Ps and getting them on the market faster.²⁴⁴ The consequences for failing to adhere to HCT/Ps regulation, however, can be severe, as experienced in 2013 by MiMedx. This publicly traded, for-profit biopharmaceutical company develops and markets regenerative and therapeutic biologics utilizing human placentas.²⁴⁵ That year, the FDA notified the company that some of its injectable products containing ground placenta (a process called micronization) could violate the law because they likely did not qualify as minimally manipulated, that is, they fell into the higher risk category.²⁴⁶ The FDA letter resulted in a sudden drop in the value of MiMedx's shares,²⁴⁷ precipitating a securities class action alleging that the company made misleading statements and falsely inflated stock market prices.²⁴⁸

The regulation of placenta as tissue is not only intricate, but also, according to bioethicist Leigh Turner and stem cell scientist Paul Knoepfler, may be underenforced.²⁴⁹ In their 2016 study of direct-to-consumer marketing of unapproved stem-cell therapies, they found that 17% of businesses marketing allogenic cell-based interventions²⁵⁰ sourced their cells from amniotic materials, 3.4% from placental tissue, and 0.6% from umbilical cords.²⁵¹ These businesses promote stem-cell interventions to treat a wide range of diseases and injuries, as well as for cosmetic applications, generating "regulatory concerns due to

243. Kazuo Yano, Alessondra T. Speidel & Masayuki Yamato, *Four Food and Drug Administration Draft Guidance Documents and the REGROW Act: A Litmus Test for Future Changes in Human Cell- and Tissue-Based Products Regulatory Policy in the United States?*, 12 J. TISSUE ENGINEERING & REGENERATIVE MED. 1579, 1580 (2018).

244. See Warning Letter from Joseph Saleski, Acting Dir., Div. of Sci. Investigations, U.S. Food & Drug Admin., to Terry A. Colip, Chief Fin. Officer, Cell Point (June 15, 2006) (finding Cell Point in violation of the regulation governing the use of investigational drugs and the conduct of clinical trials because it sponsored studies in which human subjects received investigational drug products prepared from raw human placentas with the objective of evaluating detection and treatment of apoptosis in patients with breast cancer).

245. Sara Germano, *Placenta-Products Maker MiMedx Draws FDA Attention*, WALL ST. J. (Sept. 11, 2013, 8:22 PM ET), <https://www.wsj.com/articles/placentaproducts-maker-mimedx-draws-fda-attention-1378945360> [<https://perma.cc/NGY6-8W67>]; see also PLACENTA DONATION PROGRAM, *supra* note 232.

246. *Id.*

247. *Id.*

248. *In re MiMedx Group Sec. Litig.*, No. 1:13-cv-03074-TWT, 2015 WL 5969357 (N.D. Ga. Apr. 16, 2015).

249. Leigh Turner & Paul Knoepfler, *Selling Stem Cells in the USA: Assessing the Direct-to-Consumer Industry*, 19 CELL STEM CELL 154 (2016).

250. That is, procedures in which the stem cells originate from donors other than the patients.

251. Turner & Knoepfler, *supra* note 249, at 155.

apparent noncompliance with federal regulations.”²⁵² In light of the 351 businesses they identified as actively advertising stem cells products nationally, Turner and Knoepfler “ask whether regulatory inaction has emboldened entrepreneurial physicians and other market participants.”²⁵³ In a subsequent publication, Turner observed that the market in direct-to-consumer stem cell interventions is even larger than he originally thought.²⁵⁴ Despite apparent noncompliance, few such businesses have been subject to enforcement actions by the FDA or other agencies.²⁵⁵

ii. The Placenta as Dietary Ingredient

Inasmuch as a placenta-based product is not intended to treat, cure, mitigate or prevent disease, it may come under a different regulatory regime—dietary supplements and food regulation. As early as 2000, the FDA declared that the human placenta is neither a food nor a dietary ingredient under the Federal Food, Drug, and Cosmetic Act²⁵⁶ (FD&C Act) in a warning letter to New York based Chinese medicinal herbs provider Blue Light, which had marketed two products containing placenta.²⁵⁷ The agency explained that human tissue is not “customarily used as human food or drink” and may transmit disease, concluding that a dietary or food product containing human placenta is adulterated under the statute and can therefore not be marketed in the United States.²⁵⁸ Since then, the FDA consistently reaffirmed this stance in its correspondence with other providers of Chinese medicinal herbs who included, or planned to include, human placenta in their products.²⁵⁹ Mainstream American personal care

252. *Id.* at 155–56.

253. *Id.* at 157.

254. Leigh Turner, *The US Direct-to-Consumer Marketplace for Autologous Stem Cell Interventions*, 61 *PERSP. BIOLOGY & MED.* 7, 8–9 (2018) (noting that, as of May 2017, 432 distinct U.S. businesses sell stem cell-based interventions provided at 716 clinics and that, among businesses advertising allogeneic treatment, 80 companies reportedly sourced from amniotic material, 13 from placental tissue, and 5 from umbilical cord blood).

255. *Id.* at 13.

256. This is the set of laws giving authority to the FDA to oversee the safety of food, drugs, medical devices, and cosmetics. See 21 U.S.C. § 321(f), (ff)(1) (2019).

257. Warning Letter from Edward W. Thomas, Acting Dist. Dir., N.Y. Dist. Office, U.S. Food & Drug Admin., to Chao Zhang, President, Blue Light (June 15, 2006).

258. *Id.*

259. See Warning Letter from U.S. Food & Drug Admin. to Hui Fen Li, President, N.Y. Healthy Herbs (Oct. 7, 2002) (advising that Youth Plus, a product containing human placenta intended to help “woman to revitalize her body’s feminine activities and energy” could not be marketed because it was adulterated); Warning Letter from James S. Cohen, Acting Dir., Office of Compliance & Biologics Quality, U.S. Food & Drug Admin. to Maria Anecchino, Belleza Integral (Aug. 31, 2004) (putting the company on notice that some of the products it sells online, such as its “anti-ageing vaccine” H-Ultracell, composed of human placenta, and “syringes with placental liquid of human origin” were considered drugs or biological products and therefore required a valid biologics license or new drug application to be legally marketed); U.S. Food & Drug Admin., *Herbal Science*

companies appear to have stopped using human placenta in cosmetics in the past couple of decades,²⁶⁰ but dried or ground placenta has long been a popular ingredient in traditional Chinese medicine, which may explain why the FDA enforcement actions have targeted this particular source of placenta commerce.²⁶¹ The issue came to the fore anew in 2011, when Chinese medicine manufacturer Fang Ding filed a “new dietary ingredient” (NDI) application with FDA seeking approval of a dietary supplement product called Placentake, which contained human placenta extract.²⁶² Ding was following the FDA rule according to which, if a supplement contains a dietary ingredient that has not “been present in the food supply as an article used for food in a form in which the food has not been chemically altered,” it is a “new dietary ingredient” and must undergo its own form of premarket review.²⁶³ In response to his application, the agency restated its view that a product containing human placenta is not a dietary ingredient and is as such adulterated, thus declining to take a position on its safety.²⁶⁴

International, Inc Recalls Twelve Dietary Herbal Supplements Nationwide Because Of Possible Health Risk Associated With Ephedra, Aristolochic Acid And Human Placenta, U.S. DEP'T HEALTH & HUM. SERV., (Apr. 10, 2007), <https://wayback.archive-it.org/7993/20170406122205/https://www.fda.gov/Safety/Recalls/ArchiveRecalls/2008/ucm112427.htm> [<https://perma.cc/VEX7-W98C>] (reporting that the FDA issued a warning letter to Herbal Science International because several of its dietary supplements were adulterated, including “Seng Jong Tzu Tong Tan,” because it contained human placenta); Solstice Medicine Recall Notice (Feb. 21, 2016) (noting that an herbal supplement was recalled because it contained human placenta).

260. See Renee Jacques, *You Probably Shouldn't Be Using Products with Placentas in Them*, ALLURE (July 16, 2015), <https://www.allure.com/story/placenta-beauty-products> [<https://perma.cc/CT5J-SNKK>].

261. See Zheng Xin, *E-Sales of Placenta Continue to Thrive Under Ban*, CHINA DAILY (Oct. 25, 2011, 8:15 AM), https://www.chinadaily.com.cn/china/2011-10/25/content_13966723.htm [<https://perma.cc/U8QU-AKEF>] (noting that the Chinese government has banned the trade of human placentas since 2005 on the premise that it could contribute to the spread of diseases, but that in spite of the ban “Taobao, the country’s largest online marketplace, is awash with vendors offering dried or ground placenta.”).

262. Memorandum from Dan D. Levy, Senior Microbiologist & Acting Supervisor, New Dietary Ingredient Review Team, U.S. Food & Drug Admin., to Mr. Fang Ding, Healthkord (USA) (Apr. 6, 2011) (responding to a premarket notification filed by a company that planned to market Placentake tablets containing human placenta extract).

263. 21 U.S.C. § 350b(a)(1); see also *New Dietary Ingredients in Dietary Supplements - Background for Industry*, U.S. FOOD & DRUG ADMIN. (Oct. 4, 2019), <https://www.fda.gov/food/new-dietary-ingredients-ndi-notification-process/new-dietary-ingredients-dietary-supplements-background-industry> [<https://perma.cc/5QTK-VGSA>].

264. Memorandum from Dan D. Levy to Mr. Fang Ding, *supra* note 262; see also U.S. FOOD & DRUG ADMIN., INVESTIGATIONAL NEW DRUG APPLICATIONS (INDS)—DETERMINING WHETHER HUMAN RESEARCH STUDIES CAN BE CONDUCTED WITHOUT AN IND: GUIDANCE FOR CLINICAL INVESTIGATORS, SPONSORS, AND IRBS 11 (2013) (“[A] study of the effect of a cosmetic product containing human or animal biological material (such as placenta) on skin repair mechanisms would require an IND, even if the study is intended only to support a claim of younger looking skin.”).

iii. Placentophagy, or the Placenta as Food

In contrast to commercial uses of placentas in supplements, maternal placentophagy and other forms of DIY placenta consumption are not explicitly banned by the federal government even though several agencies intervened in the past decade or so to discourage or proscribe associated practices on personal and public health and safety grounds.²⁶⁵ The FDA “has adopted a hands-off policy as long as placentas and pills don’t cross state lines,”²⁶⁶ but it has been willing to get involved when placentas are collected and prepared for consumption by people other than the donor or on a wide scale. For instance, in 2008, in conjunction with Florida state authorities, the FDA raided a Miami birthing center owned and operated by a diverse group of women,²⁶⁷ and accused the staff of mixing ground placentas from various donors into large batches and dispensing them to their postpartum patients.²⁶⁸ In other words, for now, self-consumption slips under the agency’s radar, while consumption by others may trigger scrutiny.

The business of placenta encapsulation, so far unregulated by the FDA, is thriving. Encapsulators are typically self-employed female entrepreneurs—“mumpreneurs”²⁶⁹—offering placenta preparation alongside services combining work and care such as doula work, massage, and other forms of pre- and postnatal support.²⁷⁰ The medical profession has a long history of regulating itself, both for patient protection and to maintain a monopoly over healthcare by setting standards for entry, recredentialing, and conduct.²⁷¹ In the absence of any form of occupational licensure or other laws regulating their practice, placenta

265. See *supra* note 68 and accompanying text.

266. *Florida Department of Health Joint Investigation Leads to Federal Search Warrant in Miami*, WCTV (Dec. 31, 2008, 3:55 PM), <https://www.wctv.tv/home/headlines/36945319.html> [<https://perma.cc/E52U-5LMA>] (reporting a joint FDA-Florida Department of State investigation of a Miami birthing facility that provided its clients with placenta pills made of placentas pooled from different donors as a prophylactic measure in order to mitigate or prevent postpartum depression) [hereinafter *Florida Department*].

267. See *Our Staff* . . . , MIAMI MATERNITY CTR., <https://www.miamimaternitycenter.net/staff.htm> [<https://perma.cc/3682-QWPG>].

268. See *Florida Department*, *supra* note 266. Florida state law probably helped the Department of Health to secure a warrant for enforcement operation against the birthing facility milling placenta pills, since encapsulated placenta designed for the purpose of preventing or treating a disease or illness meets the definition of a drug under the Florida Drug and Cosmetic Act, requiring a licensed pharmacist to compound and manufacture. See FLA. STAT. § 499.003(17) (2018).

269. Perrier & Fannin, *supra* note 31, at 449.

270. *Id.* at 451 (showing based on their fieldwork in Bristol that those “complementary therapies” include “hypnobirthing, pregnancy yoga, doula services, postnatal fitness training, alternative therapies, creative workshops and other forms of ‘care’ work for pregnant women and mothers.”). In my own exploration of the placenta encapsulation market in New York City, which was conducted through web searches in the spring of 2018, most placenta encapsulators are also doulas.

271. See William D. White, *Professional Self-Regulation in Medicine*, 16 VIRTUAL MENTOR: AM. MED. ASS’N J. ETHICS 275 (2014) (delineating the public and private forms of regulation of the medical profession).

encapsulators have sought to emulate the self-regulation of medicine. A few organizations, such as the Association of Placenta Preparation Arts (APPA),²⁷² the International Placenta and Postpartum Association (IPPA),²⁷³ and Placenta Benefits (PBiU)²⁷⁴ have emerged to organize the growing business. Each organization offers its own training and certification program, aspiring to high safety and ethics standards. These standards are largely unenforceable, however, as the organizations lack regulatory oversight and licensing power. Nonetheless, their goals include the creation of professional education, the exchange of knowledge, and the promotion of competence-based decision-making and professional behavior.

The Association of Placenta Preparation Arts claims that its online program is “the most comprehensive placenta preparation training available,” calling it the “Bachelor’s Degree in Placenta Arts.”²⁷⁵ Once certified, providers must abide by the Association’s Code of Ethical Conduct, which includes client confidentiality, privacy rules, and a requirement of compliance with any applicable black letter law health and safety regulations.²⁷⁶ While calling for legal compliance, the Association expects its members to make clear on all of their materials that their service “has not been evaluated by the FDA.”²⁷⁷ Similarly, the International Placenta and Postpartum Association declares that it has “trained over 3,000 placenta specialists since 2011.” It offers both in-person and distance education that covers preparation techniques such as sanitizing and adhering to OSHA guidelines for handling blood-borne pathogens.²⁷⁸

The current regulation of the placenta as a non-food or dietary ingredient, as well as the self-regulation of placenta self-consumption, seem to be functioning satisfactorily given the rarity of reported adverse events.²⁷⁹ By contrast, as the next subsection argues, the FDA’s historically lenient approach to the human placenta as a cosmetic ingredient has proved problematic due to placenta-based

272. ASS’N OF PLACENTA PREPARATION ARTS, <https://placentaassociation.com> [<https://perma.cc/G9ZT-FK59>].

273. INT’L PLACENTA & POSTPARTUM ASS’N, <https://www.ippatraining.com> [<https://perma.cc/6WG3-E864>].

274. PLACENTA BENEFITS, <https://placentabenefits.info> [<https://perma.cc/LHF4-698V>].

275. ASS’N OF PLACENTA PREPARATION ARTS, *supra* note 272.

276. *Standards*, ASS’N. OF PLACENTA PREPARATION ARTS, <https://placentaassociation.com/standards> [<https://perma.cc/CH7Y-XF3M>].

277. *Id.*

278. *Distance Self Paced Learning*, INT’L PLACENTA & POSTPARTUM ASS’N, <https://www.ippatraining.com/distance> [<https://perma.cc/AP5D-VS23>].

279. *See supra* notes 67-70 and accompanying text. *But see* Donley, *supra* note 21, at 229 (advocating for the regulation of encapsulated placenta by the FDA as a 361 HCT/P in order to avert two harms: “(1) the spread of communicable diseases resulting from improperly handled tissue and (2) the public’s deception when manufacturers claim without proof that their product will cure, mitigate, or prevent disease”).

personal care products' health risks and disproportionate use by already vulnerable groups.

iv. The Placenta as Cosmetic Ingredient

Starting in 1959 and until the 1990s, human placentas figured among the ingredients of many mainstream personal care products and beauty treatments in the United States.²⁸⁰ Today's cosmetics are more likely to be sourced from animal placentas because American companies and distributors have become wary of marketing human placenta-based products and the FDA seems more willing to intervene when they do. Human placentas continue to be used in cosmetics manufactured in East Asian countries, in particular in Japan and South Korea, where placenta-based skin whitening and anti-aging lotions are popular.²⁸¹

The cosmetic market for placental creams promising younger or whiter skin relies on entrenched forms of racial and skin-tone stratification. Charlotte Kroløkke notes that in "the Japanese cosmetic industry, a preference for whiteness and Japanese origin is embedded in the choice of 'carefully selected' Japanese-made placenta extract or in the claim of the product being '100% Japanese.'"²⁸² Worldwide, skin tone is a major marker of status and a form of symbolic capital despite national ideologies of colorblindness and racial democracy.²⁸³ Hierarchies of skin color inherited from European colonialism that systematically privilege whiteness are alive and well in North America.²⁸⁴ These hierarchies rely on the connected systemic racism and colorism—that is, a system that privileges the lighter-skinned over the darker-skinned people within a community of color.²⁸⁵ Pregnant people's reproductive labor is thus recycled into a product that perpetuates legacies of colonialism as well as "the penetration of multinational capital and Western consumer culture."²⁸⁶ One

280. Myddleton, *supra* note 140, at 202; *see also* Nair & Elmore, *supra* note 142 (noting that, as of 1998, human placenta was still found in a few cosmetic products marketed in the United States); Marianne Taylor, *Beauty May Be Only Placenta-Deep*, CHICAGO TRIBUNE, June 29, 1980, at 11 (reporting that, at the time, a significant portion of lotions and shampoos contained human placentas "collected regularly from hospitals across the nation" and that beauty salons also used placental proteins for their treatments).

281. *See* KROLØKKE, *supra* note 30, at 6.

282. *See* KROLØKKE, *supra* note 30, at 125.

283. *See* Tanya Kateri Hernández, *Envisioning the United States in the Latin American Myth of 'Racial Democracy Mestizaje'*, 11 LATIN AM. & CARIBBEAN ETHNIC STUD. 189, 189 (2016) (debunking the racial democracy myth of Latin American post racialism and connecting it to the U.S. ideology of colorblindness).

284. Evelyn Nakano Glenn, *Yearning for Witness: Transnational Circuits in the Marketing and Consumption of Skin Lighteners*, 22 GENDER & SOC'Y 281, 281 (2008).

285. *Id.*

286. *Id.* at 286.

person's placenta is transformed into an expensive product purchased by another (or the same) person who hopes to partake in some of the benefits attached to light skin. In the United States, Margaret Hunter has shown that educational attainment, income, and spousal status are related to skin color hierarchies, leading to attempts to buy "racial capital" through skin whitening creams or surgeries.²⁸⁷ There is little science corroborating the whitening effects of placenta-based products, and with a few exceptions, the existing literature concludes that the effect of placental extract on the formation of melanin is largely unknown.²⁸⁸

The use of hair products containing placenta of human or animal origin used to be relatively common in the United States.²⁸⁹ These products, however, have detrimental side effects, particularly for children, given that exposure to placental hormones is associated with premature sexual development and higher cancer risks. This risk was unevenly distributed as the primary consumers of the placenta-based products were African-American and Latina women and their children. A study conducted in the U.S. Army in the early 2000s pointed out that the use of hair products containing hormones or placenta was highly gendered, raced, and classed.²⁹⁰ More specifically, the study found the highest probability of use "among non-white female enlisted personnel"²⁹¹—that is, mostly African-American and Latinx employees who occupied a low rank in the Army

287. Margaret L. Hunter, "If You're Light You're Alright": Light Skin Color as Social Capital for Women of Color, 16 GENDER & SOC'Y 175 (2002).

288. See Hiromi Itoh,メラニン色素の制御と美白化粧品の研究開発: プラセンタの機能と美白効果 [Control of Melanin Pigment and Research and Development of Whitening Cosmetics: Functions and Whitening Effect of Placenta], 6 FRAGRANCE J. 67, 67 (1990) (suggesting that the author found a whitening effect in placenta) (Japan); Hyun-Jin Kim et al., 태반추출물이 SK30 인체 악성 흑색종 세포주의 tyrosinase, TRP-1 과 TRP-2 발현에 미치는 영향 [The Effect of Placental Extract on the Expression of Tyrosinase, TRP-1 and TRP-2 in SK30 Melanoma Cells], 41 KOR. J. DERMATOLOGY 1612, 1612 (2003) (claiming that the authors' research showed that "placental extract inhibited the melanogenesis of SK30 melanoma cells" and "showed antimelanogenic effect by inhibiting the synthesis of tyrosinase, TRP-1 and TRP-2 mRNA," and concluding that "placental extract might be a good therapeutic regimens [sic] for UV-aggravated pigment disorders including melasma"); Prajnamoy Pal et al., A Human Placental Extract: In Vivo and In Vitro Assessments of Its Melanocyte Growth and Pigment-Inducing Activities, 41 INT'L J. DERMATOLOGY 760, 760 (2002) (study conducted in India on a guinea pig and mice that purports to show that human placental extract has "therapeutic potential for the repigmentation of vitiligo patches").

289. Maryann Donovan et al., Personal Care Products that Contain Estrogens or Xenoestrogens May Increase Breast Cancer Risk, 68 MED. HYPOTHESES 756, 758 tbl.1 (2007) (noting that, as of 1994 and among the widely-used personal care products that contained estrogen, at least four skin products from the brand Nu Skin contained human placental extract).

290. Chandra M. Tiwary & John A. Ward, Use of Hair Products Containing Hormone or Placenta by US Military Personnel, 16 J. PEDIATRIC ENDOCRINOLOGY & METABOLISM 1025 (2003).

291. *Id.* at 1027.

hierarchy.²⁹² Use was more frequent among African-Americans than other racial groups.²⁹³

The raced dimension of human and animal placenta-based hair products marketing and consumption is particularly concerning for Black children given that the use of cosmetic products among children parallels use by their parents.²⁹⁴ A 1998 case study investigated the effects of hair care products containing estrogens and human or bovine placenta on four African-American girls between the ages of 1.2 years and 7.8 years.²⁹⁵ The study found that the girls began to develop breasts and pubic hair two to twenty-four months after starting to use the products and that regression of sexual characteristics occurred after they discontinued use.²⁹⁶ Maryann Donovan and her colleagues hypothesized that the use of hormone-containing personal care products “in young African American women accounts, in part, for their increased risk of breast cancer prior to menopause, by subjecting breast buds to elevated estrogen exposure during critical windows of vulnerability in utero and in early life.”²⁹⁷ They underlined that consumers were unaware of their exposure given that not all products listed hormones or placenta as an ingredient.²⁹⁸ The application of placenta-containing products thus contributed to cumulative lifetime exposure to estrogen—a risk factor for breast cancer.²⁹⁹

That human placenta-based personal care products circulated widely until recently should not come as a surprise considering the lenient federal regulation of cosmetics compared to the regulation of drugs and medical devices. The FD&C Act does not require cosmetic products and ingredients to be approved by the FDA before they go on the market.³⁰⁰ Marie Boyd and other scholars have argued that this lax regime has a disparate impact on people who identify as women and members of other excluded groups.³⁰¹ Boyd points out that though

292. *Id.* at 1031. The authors note, though, that “[t]his is more likely to be the result of the distribution of ethnic groups among the ranks than to be a direct effect of rank.” *Id.*

293. *Id.* at 1026.

294. P.A. Zimmerman, G.L. Francis & M. Poth, *Hormone-Containing Cosmetics May Cause Signs of Early Sexual Development*, 160 MIL. MED. 628 (1995) (finding, in their study of children for evaluation of sexual precocity, that all of those using hormone-containing hair-care products were Black).

295. Chandra M. Tiwary, *Premature Sexual Development in Children Following the Use of Estrogen- or Placenta-Containing Hair Products*, 37 CLINICAL PEDIATRICS 733, 737 (1998).

296. *Id.*

297. See Donovan et al., *supra* note 289, at 756.

298. *Id.* at 763-62.

299. *Id.* at 756.

300. 21 U.S.C. §§ 361-63. Color additives are the only cosmetic ingredients which must be pre-approved by the FDA.

301. See generally Marie Boyd, *Gender, Race & the Inadequate Regulation of Cosmetics*, 30 YALE J.L. & FEMINISM 275, 289 (2019) (critiquing the underregulation of cosmetics and its disproportionate impact on women, particularly women of color and low-income women).

“men use cosmetics, cosmetics are strongly associated with women and femininity, and, on average, women use more cosmetics.”³⁰² Among them, African-American women spend more than any other group on cosmetic products.³⁰³ Boyd also emphasizes that “[c]osmetic use may not be voluntary for women,” who are under various societal pressures to use them or hold jobs in the beauty industry involving exposure.³⁰⁴

The FDA’s regulation of cosmetic labeling is often the principal legal means to protect consumers, but the FDA’s regulation of placentas may not adequately safeguard non-expert consumers. The FD&C Act prohibits “misbranding” of cosmetics, which includes false or misleading labeling by claims about a product or inaccurate labeling.³⁰⁵ The FDA recommends that placental extract be identified by a name other than “placental extract,” describing its composition more accurately on the ground that consumers associate the phrase “placental extract” with certain biologically active compounds for therapeutic use.³⁰⁶ This guidance may not prove protective for consumers unfamiliar with cosmetic ingredients and the associated jargon.³⁰⁷ Products claiming to contain placental extract may also be deemed to be misbranded cosmetics if the extract has been prepared from placentas from which the hormones and other biologically active substances have been removed and the derived substance consists principally of protein.³⁰⁸

Another problem is that manufacturers have little incentive to disclose their products’ hormonal content given that the FDA regulates products listing hormones as ingredients as new drugs.³⁰⁹ Products regulated as new drugs must undergo a lengthy and multi-million-dollar approval process, including conducting several phases of clinical investigations. To compound the issue, Donovan and her co-authors observed that “manufacturers are not currently required to disclose ingredients that they consider trade secrets nor are they required to report on past formulations of their products.”³¹⁰ Until a few years

302. *Id.*

303. See Rajiv Shah & Kelly E. Taylor, *Concealing Danger: How the Regulation of Cosmetics in the United States Puts Consumers at Risk*, 23 FORDHAM ENVTL. L. REV. 203, 212 (2011).

304. See Boyd, *supra* note 301, at 290-91.

305. Food, Drug, and Cosmetic Act § 602, 21 U.S.C. § 362.

306. 21 C.F.R. § 301.530 (1995).

307. The proliferation of cosmetic dictionaries and glossaries evinces the complexity of cosmetic-related terminology. See, e.g., RUTH WINTER, A CONSUMER’S DICTIONARY OF COSMETIC INGREDIENTS: COMPLETE INFORMATION ABOUT THE HARMFUL AND DESIRABLE INGREDIENTS FOUND IN COSMETICS AND COSMECEUTICALS (7th ed. 2009).

308. See 21 C.F.R. § 310.530 (2019) (stating that “any OTC drug product that is labeled, represented, or promoted as a topically applied hormone-containing product . . . is regarded as a new drug . . . for which an approved application . . . is required for marketing.”).

309. See *id.*

310. See Donovan et al., *supra* note 289, at 764.

ago, North American distributor Flawless Beauty and Skin sold human placenta-based products in the United States, such as Laennec Human Placenta Whitening and Authentic Relumins Advance Whitening Facial Cream.³¹¹ The FDA took Flawless Beauty to court on the ground that this product as well as a dozen of others were new drugs, not cosmetics, and were misbranded given that they did not follow the new drug application process.³¹² In the 2017 consent decree entered by the U.S. District Court of New Jersey the company was ordered to stop selling, recall, and destroy its incriminated products.³¹³ Of those containing human placenta, the complaint noted that they “can harbor microbes that can cause serious infections, including hepatitis, HIV, and herpes, among others.”³¹⁴

After examining the contrasting ways in which third parties’ access and use of placentas is regulated, the next section explores whether and how people who grow placentas are allowed to repossess them.

B. The Law of Access to One’s Placenta

1. The Regulation of Placenta Release

A number of formal and informal laws and regulations at the state, local, and institutional levels control whether individuals can repossess their placentas from healthcare facilities and under what conditions.

Since 2006, a few states have enacted laws protecting birthing parents’ access to their placenta. In those states, new parents can now assert a right to obtain the release of their placenta subject to a set of requirements. The state of Hawai‘i was the first to require explicitly that hospitals allow women or their designees to take their placentas home. This legal change was the outcome of

311. See *Trendy Asian Skin Care Product Ready to Dominate the American Market*, PR NEWswire (Oct. 10, 2012, 8:30 AM ET), <https://www.prnewswire.com/news-releases/trendy-asian-skin-care-product-ready-to-dominate-the-american-market-173475281.html> [<https://perma.cc/724P-QWQG>].

312. Paul Milo, *Feds Order N.J. Companies to Stop Selling Skin-Whitening Injections, Creams*, NJ (Sept. 27, 2017), https://www.nj.com/monmouth/index.ssf/2017/09/2_jersey_companies_ordered_to_stop_selling_skin-wh.html [<https://perma.cc/QXF7-MYDC>].

313. See *Federal Judge Orders Flawless Beauty to Stop Distributing Unapproved Drugs, Recall Certain Products*, U.S. FOOD & DRUG ADMIN. (Sept. 26, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm577565.htm> [<https://perma.cc/T46N-VKVU>] (prohibiting Flawless Beauty and affiliated company RDG Imports from importing, manufacturing, or distributing any drug products until they comply with the Food, Drug, and Cosmetic Act). Products containing placental extract are considered to be misbranded drugs when their labeling contains statements implying the prevention or treatment of disease or effect on the structure or any function of the human body, such as the promise of stimulating tissue growth and removing wrinkles. See *Complaint for Permanent Injunction* at 4, *United States v. Flawless Beauty*, No. 3:17-cv-07091-PGS-TJB (D.N.J. Sept. 12, 2017); see also 21 C.F.R. § 201.300 (2019); CTR. FOR FOOD SAFETY & APPLIED NUTRITION, *COSMETIC HANDBOOK* 12-13 (1989) [hereinafter *COSMETIC HANDBOOK*].

314. *Complaint for Permanent Injunction*, *supra* note 313.

mobilization by Native Hawaiian groups after the state Department of Health decided to classify the placenta as infectious waste in 2005.³¹⁵ This designation meant that placentas could be withheld from birthing parents and their families by healthcare facilities and disposed of as other medical infectious waste despite the fact that “Native Hawaiians view the placenta with cultural significance in which the placenta is cared for in respectful ways involving ritual ceremonies and proper burial back to the earth followed by a planting of a tree symbolizing the child’s connection back to the earth.”³¹⁶ The new Hawai‘i statute, passed in 2006, does not grant an absolute right to obtain the release of one’s placenta, however. The law specifies that a placenta will only be released “[u]pon negative findings of infection or hazard after appropriate testing of the mother” and after a “release form stipulating appropriate measures” for its “safe release” has been signed by the woman or her designee.³¹⁷

Through this language of infection, risk, and safety, the placenta is legally constructed as a biological hazard, even in a state with an extensive history of safe placenta burial practices. No case of disease transmission has been reported in association with Native Hawaiians’ long tradition of handling the placenta. This safety record raises the question whether the health risk rhetoric reflects medical and legal institutions’ histories of restricting women’s agency over their bodies under the guise of protecting them, their children, and the general public. In the context of Hawai‘i, this approach also represents an enduring form of medical colonialism, whereby colonists attempt to impose their views on health and disease so as to control colonized populations.³¹⁸ Women in their reproductive capacity in particular bear the brunt of past and ongoing medical colonialism given their crucial role in population renewal and growth. Much like other aspects of women’s reproductive freedom have been constrained—whether and when to get pregnant, where and how to deliver babies, whether and how long to breastfeed—the decision of what to do with the placenta continues to be determined in part by white medical norms and values.

Since 2006, three additional states—Connecticut, Oregon, and Texas—have enacted legislation allowing the birth family to obtain a placenta from a healthcare facility.³¹⁹ Similar to Hawai‘i, these states only permit release of the placenta after the birthing parent has tested negative for infectious diseases,

315. See Lauer, *supra* note 17.

316. See Celia T. Bardwell-Jones, *Placental Ethics: Addressing Colonial Legacies and Imagining Culturally Safe Responses to Health Care in Hawai‘i*, 13 *PLURALIST* 97, 97 (2018).

317. HAW. REV. STAT. § 321-30 (2018).

318. ARTHUR W. FRANK, *THE WOUNDED STORYTELLER: BODY, ILLNESS, AND ETHICS* 10 (1997) (“Just as political and economic colonialism took over geographic areas, modernist medicine claimed the body of its patient as its territory.”).

319. CONN. GEN. STAT. § 19a-490v (2018); OR. REV. STAT. § 459.400 (2018); OR. ADMIN. R. 333-056-0045 (2018); TEX. HEALTH & SAFETY CODE ANN. § 172.002 (2018); 25 Tex. Admin. Code § 137.38 (West 2019).

signed a release form, and been instructed on proper handling. They add the condition that the placenta is for personal, not commercial use.³²⁰ Each individual state includes its own additional restrictions. For instance, in Connecticut, physicians can send the placenta to pathology for examination against the will of the postpartum parent and their spouse.³²¹ Release after examination by the pathology department is usually not recommended because placentas are typically retained for several weeks and fixed in formalin, rendering them toxic and therefore unusable for ingestion or external application.³²²

Short of legislating, a few other states have developed guidelines or different forms of regulations for placenta release. For example, in 2010, the Massachusetts Department of Public Health issued a guidance document to healthcare facilities throughout the state holding that placentas claimed by patients were not “discarded” materials within the meaning of the state’s waste statute.³²³ Placentas can therefore be released on similar terms as in Hawai‘i, Connecticut, Oregon, and Texas. So long as no infectious risks have been established, Massachusetts patients can repossess their placenta after being provided instructions on safe handling, signing a written authorization, and packing it in a designated, labeled container.³²⁴ Also in 2010, the New York State Department of Health released an unofficial statement to the effect that hospitals and medical facilities may, at the request of a patient or patient’s representative, return a “healthy placenta” for disposition by the patient without violating any New York public health law or regulation.³²⁵ Birthing parents and their families should no longer need to reclaim their placenta from the morgue or a funeral director as some facilities used to require.³²⁶

Still other states allow for the placenta to be released under more specific circumstances. Arkansas, for example, permits a physician who has separated human tissue from other medical waste to “authorize disposition of the human

320. *Id.*; see also TEX. ADMIN. CODE § 138.3 (2018) (exempting “placentas designated for sale and obtained from a licensed hospital or a licensed birthing center” from the medical disposal requirements, but not specifying the process through which a placenta is designated for sale).

321. CONN. GEN. STAT. § 19a-490v (2018).

322. Rebecca N. Baergen, Harshwardhan M. Thaker & Debra S. Heller, *Placental Release or Disposal?: Experiences of Perinatal Pathologists*, 16 PEDIATRIC & DEVELOPMENTAL PATHOLOGY 327, 328-29 (2013).

323. Memorandum from Lauren Smith, Med. Dir. & Chief Med. Officer, and Alfred DeMaria, Med. Dir., Mass. Exec. Office of Health & Human Serv., Dep’t of Pub. Health, to CEOs of hosp. licensed to provide maternal & newborn serv. (Oct. 25, 2010), <https://www.mass.gov/files/documents/2016/07/tj/placenta-guidance.pdf> [<https://perma.cc/8WER-HNDQ>].

324. *Id.*

325. See Sumathi Reddy, *It’s a Boy! And a Placenta*, WALL ST. J. (Mar. 3, 2012, 1:41 AM ET), <https://www.wsj.com/articles/SB10001424052970203753704577257721512863662> [<https://perma.cc/P5U5-7DLT>].

326. *Id.*

tissue in a respectful and proper manner,” including releasing the placenta to the patient.³²⁷ Maryland excepts “fetuses and placentas that are released to a funeral director or parent” from its medical waste requirements, although it is unclear from the statutes and regulations what the release protocol entails.³²⁸ New Jersey exempts anatomical organs and body parts (which may include placentas) from the state’s medical waste disposal requirements if the owner’s intent is to inter or cremate them.³²⁹ New Mexico requires that freestanding birth centers develop policies and procedures for “safe handling of the placenta for families requesting to keep the placenta,” permitting its release without a court order.³³⁰

Even in states that have no law on the books pertaining to placenta release, based on the principle according to which everything which is not forbidden is allowed, birthing parents should be able to obtain the release of their placenta in the absence of contrary state statutes, regulations, or guidance documents.³³¹ Doula Courtney Durfee³³² created a google spreadsheet in 2010 to “better understand the state and regional variations in placenta release regulations and protocols.”³³³ Durfee obtained information by contacting state officials (such as local departments of health and EPA offices) and hospital staff (pathologists, infection control nurses, and lab directors) to inquire about the policies in place in their state. The document is not up-to-date, but in most states informers reported that due to the inexistence of specific legal provisions on the placenta,

327. ARK. CODE ANN. § 20-17-801(a)(1)(B) (West 2019) (specifying that patients or their designees can make a written request that their human tissues be returned to them and explicitly defining human tissue to include the placenta); § 20-17-801(a)(2) (providing that “[h]uman tissue shall not be delivered except as may be permitted by rules of the State Board of Health,” although there do not appear to be any rules of the State Board of Health related to placenta). Mississippi seems to follow a similar legal regime. See MISS. CODE ANN. § 41-39-1 (2019) (providing that patients or their designees can make a written request that “any tissue of the human body” be delivered to them after scientific examination by a physician, explicitly including placenta). As suggested by the example of Jordan Thiering discussed *supra* p. 5, this Mississippi provision may not have been consistently interpreted as supporting the release of placentas. Nevertheless, the Thiering case seems to have led to a policy change allowing hospitals and birthing centers to adopt their own internal policies on the release of placentas. See Corky Siemaszko, *Mississippi Mom Gets State to Change Placenta Policy*, NBC NEWS (Sept. 16, 2016, 12:17 PM MST), <https://www.nbcnews.com/news/us-news/mississippi-mom-gets-state-change-placenta-policy-n649596> [<https://perma.cc/PB8V-ZKAX>].

328. MD. CODE REGS. 10.06.06.01 (2018).

329. N.J. ADMIN. CODE § 7:26-3A.6 (2018). This code does not explicitly mention placentas, but may apply to placentas as organs.

330. N.M. CODE R. § 7.10.2.23 (LexisNexis 2019).

331. See Jeremy Waldron, *The Rule of Law*, STAN. ENCYCLOPEDIA PHIL. (June 22, 2016), <https://plato.stanford.edu/entries/rule-of-law> [<https://perma.cc/5FZW-H8GR>] (noting “the Rule of Law generates a presumption in favor of liberty: everything which is not expressly prohibited is permitted”).

332. See *About Us*, CD DOULA SERVICES, <https://www.cddoula.com/about-me.php> [<https://perma.cc/Q5RT-D89G>].

333. Courtney Durfee, *US Placenta Laws*, GOOGLE DOCS (2010), https://docs.google.com/spreadsheets/d/1IFz9ePkYlllxSlckq679EF3luy44RTB3h_uU23pU6m0 [<https://perma.cc/S3ZC-PCVL>].

patients should be able to obtain its release. Depending on the state, Durfee reports that individuals need to comply with hospital policies such as testing negative for diseases, signing a waiver form, or demonstrating that their request is motivated by cultural or religious beliefs.

In addition to traditional, legally binding rules, the placenta is the object of a growing body of regulations emanating from healthcare facilities or intermediaries involved in placenta consumption. OBGYNs, labor and delivery doctors, midwives, nurses, pathologists, and other medical personnel have devised policies to allow or prevent patients from taking their placentas home.³³⁴ Weill Cornell Chief of Perinatal and Obstetric Pathology Rebecca Baergen and her colleagues surveyed thirty-six practicing perinatal pathologists in the United States and Canada in 2013 to investigate policies in place for the release of placentas.³³⁵ Most respondents (66%) stated that their institution allowed the release of placentas, but 11% reported that theirs specifically prevented release. Increasingly, healthcare facilities have developed formal guidelines to address issues of liability and to comply with the relevant law on the handling and disposal of infectious waste. These internal rules and policies cover issues such as whether and under what conditions placental tissue can be released to patients or used for research or other purposes. They are rarely public, representing a hidden form of placenta law. Patients typically find out about how their placental tissue will be handled only if they are solicited for donation or specifically inquire about taking it home.

A few healthcare systems have made their placenta release policies public, however, revealing wide differences in this uncoordinated body of semi-hidden law. Some restrict the purpose for which the placenta can be released; others restrict the timing; still others delineate the type of container to be used and the location where the placenta can be consumed. For instance, the Association of Washington Public Hospital Districts, which serves as the trade association for Washington State's public hospital districts, requires that placentas remain stored at the hospital for one week after delivery so that they can be sent for pathological examination should the newborn develop complications.³³⁶ Placentas can be released after that, but by then it could be too late for people wishing to eat or encapsulate theirs fresh.³³⁷ The Naval Medical Center

334. See Bardwell-Jones, *supra* note 316, at 99 (noting that even before Hawai'i explicitly protected women's and families' rights to recover their placentas from healthcare facilities, Hawaiian doctors discretely allowed them to take the placentas off hospital premises); see also Abrahamian, *supra* note 55 (reporting that New York hospitals refused to return placentas to patients as recently as 2011).

335. See Baergen, Thaker & Heller, *supra* note 322.

336. *Policy Regarding Placentas*, ASS'N WASH. PUB. HOSP. DISTRICTS (Oct. 9, 2000), <https://www.awphd.org/wp-content/uploads/2017/05/Placentas.pdf> [<https://perma.cc/5LSX-G576>].

337. *Placenta Encapsulation FAQ*, ABC DOULA SERV. (2018), <https://www.abcdoula.com/postpartum-service/placenta-encapsulation-faqs> [<https://perma.cc/J48Z-QPQ6>] (advising women to ask hospitals that retain placentas for seven to fifteen days postpartum to freeze them so that the

Portsmouth, the U.S. Navy's oldest hospital, which includes ten branches and clinics in Virginia, limits release to requests "based on cultural and religious beliefs."³³⁸ Allina Health, a care system that owns and operates thirteen hospitals and dozens of clinics throughout Minnesota and Wisconsin, issued a comparatively liberal policy in 2017, allowing patients to take possession of their placenta so long as they consume it in the delivery room.³³⁹

In addition to this patchwork of laws governing placenta release directly, individuals' access to their placenta may also be regulated indirectly via state fetal burial laws typically aimed at curbing the right to abortion, which are discussed in the next section.

2. Fetal Burial Laws

The law of placenta has become embroiled in antiabortion politics via restrictions on the disposition of fetal remains in a way that highlights the intersection of reproductive justice and placenta access. In some states, fetal tissue is assimilated to other forms of medical wastes in terms of hazard perception and treatment,³⁴⁰ and therefore disposed of in the same fashion. It is typically sent to medical waste disposal companies to be incinerated or disposed of through other methods.³⁴¹ In other states, fetal burial laws have spread that allow patients to repossess or direct the disposal of their fetal remains via burial, entombment, and cremation, or mandate medical facilities to handle fetal remains in similar ways, excluding them from standard management of medical waste. As part of the growing movement for fetal legal personhood in particular, several jurisdictions imposed stringent limitations on the use of fetal tissue during the 2016 legislative session.³⁴² These laws are often inspired by model legislation compiled by Americans United for Life, a pro-life public interest group aimed at treating dead embryos and fetuses as deceased persons for the

placentas can still be consumed upon release or be encapsulated, as the process of encapsulation must in principle start within twenty-four to forty-eight hours postpartum).

338. Labor & Delivery Unit, *Removal of Placenta From Hospital Per Patient's Request*, NAVY MED. 1 (Dec. 2011), <https://www.med.navy.mil/sites/nmcp/Dept/Shared%20Documents/QualityManagement/ICM/315-Ch3-LD-SOP-for-removal-of-placenta-from-hospital-per-patients-request.pdf> [<https://perma.cc/M76T-NU2J>].

339. ALLINA HEALTH, SYSTEM-WIDE POLICY: PLACENTA HANDLING (Jan. 2017).

340. See Mallory Duncan, *Indiana Fetal Remains Bill Puts Spotlight on Fetal Disposal*, WISHTV (Feb. 21, 2016, 4:45 PM EST), <https://wishtv.com/2016/02/21/indiana-fetal-remains-bill-puts-spotlight-on-fetal-disposal> [<https://perma.cc/VX8G-PKJM>] ("Most states treat fetal tissue from an abortion as medical waste because it's typically considered to be infectious or potentially infectious").

341. See Kimball Key, *supra* note 197, at 314-15 (2017) (discussing the laws pertaining to the disposal of fetal remains).

342. *Id.* at 309-10.

purpose of disposal laws.³⁴³ Some versions mandate that fetal remains from abortions and miscarriages be interred or cremated as the only “dignified” way to dispose of a fetus, and are backed by criminal sanctions.³⁴⁴ Providers of obstetrical services must thus dispose of fetal remains in the same manner as cadavers, that is, by burial, interment, or cremation. The requirement poses logistical and financial challenges considering that fetal cremations can cost around \$500 each and burials more than twice that figure.³⁴⁵

Different states define fetal tissue differently, with some explicitly including the placenta in their definition, others explicitly excluding it, and still others saying nothing at all about placentas. The resulting paradox is that in some states legislation that restricts patients’ choice when it comes to whether, how, and when to terminate their pregnancy may result in *more* choice when it comes to deciding what to do with their placenta in the context of pregnancy termination and loss than live or still birth. The relevant Indiana statute,³⁴⁶ for example, empowers patients who had a miscarriage or an abortion to decide the final disposition of the deceased fetus, allowing them the option to take possession of the related placenta; yet the state does not guarantee patients who have live or stillbirths the same option.³⁴⁷ Louisiana permits people who undergo abortions or experience a miscarriage to arrange for the final disposition the fetal remains,³⁴⁸ which presumably include the placenta,³⁴⁹ but does not codify the same option for full-term deliveries. Conversely, in other states, patients may end up having more decision-making autonomy over their dead fetuses narrowly defined than over their placentas. This is the case in jurisdictions that specify that fetal remains should be handled separately from medical waste, without including the placenta in the definition of fetal remains, resulting in patients’ being able to make decisions as to the disposal of the fetus but not its related placenta.³⁵⁰ The issue of the disparate treatment between placentas and other

343. *Id.* at 319.

344. *Id.*

345. See Dov Fox, I. Glenn Cohen & Eli Y. Adashi, *The Law and Ethics of Fetal Burial Requirements for Reproductive Health Care*, 322 J. AM. MED. ASS’N 1347, 1347 (2019).

346. The Supreme Court upheld the portion of the statute excluding fetal remains from the definition of infectious and pathological waste, thereby requiring abortion providers to bury or cremate fetal remains in *Box v. Planned Parenthood of Indiana and Kentucky*, 587 U.S. ___, 139 S. Ct. 1780 (2019).

347. IND. CODE ANN. § 16-34-3-2 (West 2017).

348. LA. ADMIN. CODE tit. 48, § 4431 (2019); see also LA. STAT. ANN. § 40:1191.2 (2019).

349. LA. ADMIN. CODE tit. 48, § 4401 (2019) (defining “Products of Conception” as “placenta, amniotic sac or membrane, embryo, or fetal elements that result from a human pregnancy”).

350. Illinois is such a state, as it specifically requires that someone experiencing a miscarriage at less than twenty weeks of gestation have the “right to arrange for the burial or cremation of the fetus,” see ILL. ADMIN. CODE tit. 77, § 500.50 (2019), but no right to the placenta, which is explicitly defined as pathological waste and must “be disposed of by a waste hauler with a permit from the Illinois Environmental Protection Agency,” see ILL. ADMIN. CODE tit. 77, § 265.2050 (2019). See also ALA. CODE § 26-23F-4 (2019) (providing that “[t]he mother, father, or authorized representative may

fetal tissues, on the one hand, and between the treatment of fetal tissues and placentas in the context of abortions, miscarriages and live or still births, on the other hand, has not been challenged in court. However, in its 2019 *Box* decision, the Supreme Court upheld Indiana's statute requiring interment or cremation of fetal remains in a *per curiam* opinion, overturning the Seventh Circuit below.³⁵¹ The Court applied the rational basis standard on the ground that no fundamental right was implicated by the fetal remains provision. The statute met the test, in the Court's view, as states have a "legitimate interest in proper disposal of fetal remains"³⁵² and the provision at stake, though "not perfectly tailored," was sufficiently rational.³⁵³

3. A Fundamental Right to One's Placenta?

Is the Supreme Court correct that no fundamental right is involved in the disposal of fetal tissues, placenta included? A full discussion of the regulation of fetal tissues would take me too far afield, but as others have argued, restricting individuals' decision-making over their placenta infringes upon their individual rights over their bodies and life.³⁵⁴ Pregnant people grow placentas with their own bodies and the organ has a symbolic meaning that transcends its materiality. It is meaning-making in such a way that preventing access to it can profoundly

request the release of the bodily remains to the mother, father, or authorized representative for dignified final disposition by burial, interment, or cremation," but not stating whether "bodily remains" include placentas); COLO. REV. STAT. ANN. § 25-2-110.5 (West 2019) (providing that "[i]n every instance of fetal death, the health care provider, upon request of the pregnant woman, shall release to the woman or the woman's designee the remains of a fetal death for final disposition in accordance with applicable law," but not stating whether placentas are included in the definition of medical waste in COLO. CODE REGS. § 1007-2:1-1.2 (2019)); IDAHO CODE ANN. § 39-9304 (West 2019) (allowing patients and their representatives "to direct the receipt and disposition of [the] deceased unborn infant's bodily remains" in cases of miscarriage and stillbirth without specifying whether those remains include the placenta); MICH. COMP. LAWS ANN. § 333.2848 (West 2019) (entitling parents to direct the final disposition of a dead fetus by interment or cremation); MICH. COMP. LAWS ANN. § 333.13807 (West 2019) (defining the placenta as a "product of conception" distinct from the "fetus or fetal body parts"); MINN. STAT. § 137.47 (2019) (defines "fetal tissue" as not "includ[ing] tissue or cells obtained from a placenta, umbilical cord or amniotic fluid"); MINN. STAT. ANN. § 145.1621 (West 2019) (providing for the dignified and sanitary disposition of the remains of aborted or miscarried human fetuses); MISS. CODE ANN. § 41-39-1 (West 2019) (allowing "the mother of the dead foetus or her spouse" to object to its disposal as standard medical waste, but indicating that "a dead foetus is defined as a product of human conception, exclusive of its placenta"); OKLA. STAT. ANN. tit. 63, § 3129 (West 2019) (providing that a "parent of the child shall have the right to direct the disposition of the remains"); OKLA. ADMIN. CODE § 310:616-5-2 (2019) (defining placentas as biomedical waste);

351. *Box*, 587 U.S.

352. *City of Akron v. Akron Ctr. for Reprod. Health*, 462 U.S. 416, 452 n.45 (1983).

353. *Box*, 587 U.S. at 2.

354. See Lynnea Shrief, *Before You Judge or Scrunch up Your Face, Just Let Me Explain Why I Ate and Drank My Child's Placenta*, INDEP. (Mar. 20, 2015, 4:09 PM), <https://www.independent.co.uk/voices/comment/before-you-judge-or-scrunch-up-your-face-just-let-me-explain-why-i-ate-and-drank-my-childs-placenta-10123099.html> [<https://perma.cc/7SHY-D4SS>] (framing placenta consumption as a woman's "right").

violate an individual's right to make decisions affecting their body, intimacy, and privacy.

The right to repossess one's placenta, or at least make informed decisions as to who can access it and under what conditions, could be understood under a property or privacy right framework, or both. Radhika Rao has shown that the property and privacy constructions of the body overlap in that both protect the same interests—the right to possess one's own body.³⁵⁵ Under a property theory, interfering with patients' access to their own placentas or taking placenta without asking for their informed consent would be a deprivation of bodily property or "taking" requiring the payment of just compensation under the Fifth and the Fourteenth Amendments.³⁵⁶ Amber Goeden thus argues in favor of a property right in placentas granting women full access protected by a carve-out in OSHA regulations.³⁵⁷ Another approach would be to conceive of people's interest in their placentas as falling under the umbrella of constitutional privacy,³⁵⁸ on the model of the rights to marriage, contraception, or abortion.³⁵⁹ Privacy not only guarantees individuals a certain degree of autonomy over their bodies, but also safeguards the freedom to make certain decisions free from governmental interference—be it to refuse that their fetal remains be cremated or buried or to take possession of their fetal tissues, including their placenta. Under both theories, laws or regulations depriving pregnant people of the right to choose what to do with their placentas would be subject to strict scrutiny.

Restricting people's access to their placentas could also be held to violate another type of right—collective cultural and religious rights.³⁶⁰ Current law, along with mainstream, medically-oriented birthing practices, represent forms of enduring colonialism for people and communities for whom the placenta has cultural or religious significance.³⁶¹ Writing about the case of Hawai'i, Celia Bardwell-Jones emphasizes that the placenta must be thought of in the context of the history of colonization and the rejection of native Hawaiian mothering and

355. Radhika Rao, *Property, Privacy, and the Human Body*, 80 B.U. L. REV. 359, 366-367 (2000).

356. This theory is likely to fail in court given the *Moore* precedent. See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990) (finding that the patient had no property interest in his own bodily cells, while scientists who developed products from the patient's cells had a property interest in them).

357. See Goeden, *supra* note 21, at 190-98.

358. *Griswold v. Connecticut*, 381 U.S. 479, 484 (1965) (holding that various constitutional provisions "create zones of privacy").

359. *Id.*; *Zablocki v. Redhail*, 434 U.S. 374, 384 (1978) (categorizing "the decision to marry as among the personal decisions protected by the right of privacy"); *Roe v. Wade*, 410 U.S. 113 (1973) (establishing a right to abortion as part of the broader right to privacy).

360. See generally Yvonne Donders, *Foundations of Collective Cultural Rights in International Human Rights Law*, in *CULTURAL RIGHTS AS COLLECTIVE RIGHTS: AN INTERNATIONAL LAW PERSPECTIVE* 87 (Andrzej Jakubowski ed., 2016).

361. See *supra* note 318 and accompanying text.

birthing practices.³⁶² She points out that in native Hawaiian culture, “the moral virtue of the child is dependent on the proper care of the placenta. Understanding the placenta as biological waste already places the child in a moral crisis throughout its life.”³⁶³ Some medical providers are sensitive to the specific birthing needs of their patients. For example, the Metropolitan Chicago Healthcare Council adopted “Guidelines for Healthcare Providers Interacting With American Indian (Native American; First Nation) Patients and Their Families,” which include “saving of the placenta.”³⁶⁴ But in other medical settings, securing the release of a placenta, even for cultural and religious reasons, remains an uphill battle.

Until recently, individuals who valued and retained their placentas for cultural and spiritual reasons were primarily from African, Asian, Latinx, and Native American backgrounds. Today, though, affluent, college-educated white women are the most likely to secure access to their placentas.³⁶⁵ Accessing one’s placenta requires resources—social, financial, and epistemic. Patients typically need to research whether release is authorized and on what conditions; they must sometimes pay fees to repossess their placenta, for example when they are only released to licensed funeral directors commanding a fee or after a court order.³⁶⁶ Birthing parents wishing to ingest their placentas often hire encapsulators, which is not only costly,³⁶⁷ but also requires its own administrative labor of researching and interviewing providers. They and their families are also responsible for ensuring that the placenta is collected and stored properly. This entails arranging for a container (and sometimes a cooler when the facility provides neither ice nor refrigeration) as well as assigning someone the task of transporting the placenta home soon after the birth.

Accordingly, placentophagy has been critiqued as a neo-liberal or capitalist form of consumption associated with intensive motherhood, the dominant

362. See Bardwell-Jones, *supra* note 316.

363. *Id.* at 106.

364. *Guidelines for Healthcare Providers Interacting with American Indian (Native American; First Nation) Patients and Their Families*, METROPOLITAN CHI. HEALTHCARE COUNCIL (2004), https://www.kyha.com/assets/docs/PreparednessDocs/cg-native_american.pdf [<https://perma.cc/Z9B9-39XS>].

365. Granted, I know of no empirical studies quantifying placenta-release requests based on race, ethnicity, or class. Nor are there data available on the motivations behind requests for release. See Selander et al., *supra* note 52; *supra* note 85 and accompanying text (providing demographics of women encapsulating and eating their placentas, not of women requesting the release of their placentas).

366. See Arielle Pardes, *Hospital Regulations Are Forcing Women to Steal Their Own Placentas*, VICE (Sept. 24, 2014, 11:08 AM), https://www.vice.com/en_us/article/xd57m3/heres-why-women-are-stealing-their-own-placentas-924 [<https://perma.cc/EL2Y-M8X9>] (noting that, in Austin, Texas it would have cost one of the women interviewed \$250 to obtain her placenta via a court order and “slightly less” to have it sent to the morgue).

367. See Farr et al., *supra* note 67, at 403.

mothering ideology among middle-class white women.³⁶⁸ Intensive motherhood holds individual mothers primarily responsible for child-rearing through a process which is child-centered, expert-guided, emotionally absorbing, labor-intensive, and expensive.³⁶⁹ The temporal range of mothers' responsibility toward their children's health has been extended by medical advances to begin prior to conception and to continue throughout pregnancy and beyond. Maria Fannin has argued that private cord banking promotes a form of "hoarding" of biological materials by encouraging parents to withdraw their donation from public banks.³⁷⁰ Her arguments apply equally to placentas. The private banking of placentas represents an extreme form of intensive mothering.³⁷¹ Today's responsible mother is supposed to protect her children from future diseases and to preserve potentially valuable biological materials for them. The maternal experience is also increasingly a consumer's experience, especially for white, middle-class, cisgender, straight mothers—it's about which products, services, diagnostic tests they choose to purchase. Placentophagy figures among a range of products and services aimed at pregnant or newly parent consumers—from prenatal testing and yoga to postpartum doulas and massages.³⁷² Diane Negra argues that these consumption practices reinforce class exclusions, as this form of consumerism is only available to the affluent able to devote substantial amounts of time and money to their children.³⁷³

This Part has argued that the placenta is regulated by a hodgepodge of laws, regulations, and policies which sometimes conflict and yield counterintuitive results. Placental economies exhibit convoluted circuits of sourcing, processing, and distribution, with placentas classified and reclassified alternatively as waste or highly valuable substance depending on the context and identity of those seeking to obtain it. The inequities at work in these practices call for further explorations with an eye toward legal change.

368. See Kroløkke, Dickinson, & Foss, *supra* note 208, at 147-48.

369. SHARON HAYS, *THE CULTURAL CONTRADICTIONS OF MOTHERHOOD* (1998) (identifying and critiquing the phenomenon of intensive mothering).

370. Maria Fannin, *The Hoarding Economy of Endometrial Stem Cell Storage*, 19 *BODY & SOC'Y* 32 (2013).

371. See KROLØKKE, *supra* note 30, at 131.

372. See Gillian Hewitson, *The Commodified Womb and Neoliberal Families*, 46 *REV. RADICAL POL. ECON.* 489 (2014); see also *MOTHERHOOD, MARKETS AND CONSUMPTION: THE MAKING OF MOTHERS IN CONTEMPORARY WESTERN CULTURES* (Stephanie O'Donohoe et al. eds., 2013) (on the construction of pregnant women as specific types of consumers).

373. DIANE NEGRA, *WHAT A GIRL WANTS? FANTASIZING THE RECLAMATION OF SELF IN POSTFEMINISM* 9-10 (2009).

III. ALTERNATIVE PLACENTA REGULATION

Rebecca Yoshizawa asks “*who* is empowered to define the terms and conditions under which the placenta is collected and utilized in science and medicine[?]”³⁷⁴ To answer her question and identify a range of best practices that public and private institutions might develop, more empirical data is needed on the conditions under which placental tissue is collected, processed, and distributed as well as on donors’ attitudes and preferences. What happens to placentas which remain unclaimed? What percentage are discarded versus donated or sold? How are the donation or sale agreements negotiated between healthcare facilities and third parties and what are their customary terms? There is much more we must know about the circulation of placentas outside the body and across supply chains before we can reach any firm conclusions about the best way to proceed. But knowing the possible pathways forward should help stakeholders make better choices in the present. After presenting various choice architectures for placenta decisions, including how decisions are framed and whether donors should be compensated, this Part explores avenues for regulating third parties’ access to and use of placentas.

A. Designing a New Choice Regime

1. Protecting Freedom of Choice

Under current legal regimes, neither federal nor state law recognize individual ownership rights in human tissue samples used in medical research.³⁷⁵ Though there are state-to-state and healthcare facility-to-healthcare facility variations, pregnant individuals are usually presumed to abandon their placentas to the facility caring for them. This is not specific to the context of pregnancy and placentas. Most medical centers require that patients admitted for treatment or testing sign blanket consent forms stating that all their data or tissue samples belong to the doctor or institution.³⁷⁶ In theory, patients can strike clauses they disagree with, but most may feel too intimidated and vulnerable at a time when they might feel sick, pained, or frightened, and the staff may not allow them to do so.³⁷⁷ This state of affairs fails to provide patients with freedom of choice in the form of a meaningful opt-in or opt-out. They may be uninformed

374. Yoshizawa, *supra* note 29, at 11.

375. See, e.g., *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990); see also Rina Hakimian & David Korn, *Ownership and Use of Tissue Specimens for Research*, 292 J. AM. MED. ASS’N. 2500 (2004) (explaining that when a body part or tissue has been extracted for diagnostic or clinical purposes, it is thought to come under the ownership of the health care provider).

376. See Petrow, *supra* note 13.

377. *Id.*

as to the fate of their placenta, lack the knowledge that they can opt out, or lack the opportunity to opt out. Considering the demographic characteristics of those who eat and encapsulate their placentas, there is a possibility that a greater share of the placentas collected for research and other purposes originate from less privileged or already marginalized groups. This discrepancy would not be unprecedented. Michele Goodwin has shown that, in the context of organ donation, Blacks and Latinxs are the overwhelming majority of presumed-consent donors in some states.³⁷⁸ She also suggested that even when women are consulted on the donation of their placentas, their decision may not be fully voluntary, writing, “the consent processes involved with these tissue donations are frequently illusive. Hospitals, for example, may condition treatment on a patient waiving her right to recover or destroy her tissue, including placentas.”³⁷⁹

In thinking about redesigning placenta decision-making frameworks, competing values are at stake. Should the new rules be chosen based on whether they promote patients’ autonomy, public health, or third parties’ access? Are there relevant differences among pregnant people that would justify applying personalized rules for some of them and not others? Various avenues are available to the “choice architects,” Cass Sunstein’s term for the people or institutions who design the social backgrounds against which individual choices are made.³⁸⁰ The two approaches that secure the most autonomy are default rules (understood as interventions that do not impose mandates or bans, but nonetheless incline people’s choices in a particular direction) and active choosing (in which people are asked or required to make decisions on their own).³⁸¹

Among default rules, two opposite versions of the background rule could be set. The first would be for pregnant people to opt in, that is, to be specifically asked to give their consent for their placenta to be donated, destroyed, or used in any other way.³⁸² Consent would not be presumed. The second would be for them to opt out. Their consent to donating their placenta to the healthcare facility, whatever its future use, would be presumed. This default would require them to object explicitly if they do not want to destroy or donate their placenta, but rather

378. Michele Goodwin, *Empires of the Flesh: Tissue and Organ Taboos*, 60 ALA. L. REV. 1219, 1238 (2009).

379. *Id.* at 1235.

380. Cass R. Sunstein, *Deciding by Default*, 162 U. PA. L. REV. 1, 5 (2013).

381. *Id.*

382. See generally Lior Jacob Strahilevitz, *The Right to Destroy*, 114 YALE L.J. 781 (2005) (showing that the concept of property ownership has long included the right for proprietors to destroy their property, even if current American law has restricted this feature in the past decades on the ground that valuable resources must not be wasted). A woman’s decision to destroy the placenta would ensure that she permanently excludes third parties from using it. The argument that destroying women’s placentas wastes a valuable social resource is ill-founded given that many legal regimes classify placentas as waste.

want it released to them. Alternatively, active choosing would directly elicit patients' preferences. They would be asked to make an explicit choice among various options, such as the following: keeping their placenta, donating it for a variety of purposes (research, medical, or commercial use), or relinquishing it at the facility for disposal or storage.³⁸³ Should they decline to choose, one of the two default rules could be applied.

These different choice architectures have costs and benefits. Defaults save a great deal of time and efforts to all involved, but they are notoriously sticky.³⁸⁴ The current law of post-mortem transplantable organ donation is based on an opt-in default. This results in most transplantable organs in the nation being destroyed because a majority of Americans have not opted into donation even though they have no more use for their organs.³⁸⁵ This is in contrast to certain European countries where donating organs is the default and people must affirmatively opt out, resulting in much higher organ donation rates.³⁸⁶ Similarly, an opt-in regime for placentas, while protecting patients' agency, could diminish the number of placentas available to third parties, in particular researchers and doctors engaged in socially useful activities. An explicit opt-out default would likely produce significant benefits for third parties by ensuring the continuing availability and affordability of placental tissue. It could also benefit patients and their families when placentas remain stored at the pathology department and become useful for diagnostic or clinical care down the line in cases of pregnancy complication or when the child becomes sick or develops disabilities.³⁸⁷ An opt-out framework would differ from the status quo in that pregnant people would have access to information that explicitly presents the option to opt-out of keeping a placenta rather presuming that they opt out. Patients' freedom of choice would be preserved, however, as the default would allow those who have intense preferences to make their voice heard.³⁸⁸

Overall, active choosing would be most protective of individuals who want to avoid any kind of steering by the government or healthcare providers. It could be used to promote learning about the placenta and its uses via information provided in support of the various options open for choice. That said, active

383. This could take the form of menus that offer decisionmakers a series of options. See generally Ian Ayres, *Menu Matter*, 73 U. CHI. L. REV. 3 (2006) (exploring the regulation of menus).

384. See Sunstein, *supra* note 380, at 12 n.42 (explaining that default rules are often "sticky"—that is, they establish a "reference point" from which decisionmakers do not like to move).

385. Richard H. Thaler & Cass. R. Sunstein, *Libertarian Paternalism Is Not an Oxymoron* (Univ. of Chi. Working Paper No. 43, 2003).

386. See generally Eric J. Johnson & Daniel Goldstein, *Do Defaults Save Lives?*, 302 SCIENCE 1338 (2003) (comparing organ donation in presumed-consent and explicit-consent countries).

387. See, e.g., Jennifer K. Straughen et al., *The Association Between Placental Histopathology and Autism Spectrum Disorder*, 57 PLACENTA 183 (2017) (arguing that placental assessment may provide important insights into autism spectrum disorder).

388. See Sunstein, *supra* note 380, at 33-34 (2013) (discussing how people with intense preferences fare in opt-out systems).

choosing itself is not neutral and people's decisions may be affected by how the various options are presented, such as the order and number of options. Active choosing could also prove burdensome to patients, who already face difficult decisions, producing confusion and frustration, and wasting time and effort.³⁸⁹ Until more information surfaces on the operation of the placenta markets, I would favor adopting an opt-out regime all the while consciously experimenting with the two other approaches so as to track and study the results.

2. *How Much Freedom of Choice?*

Should the right to obtain one's placenta be unconditional or should it be balanced against other considerations such as the risk of contamination (to the patients themselves, but also to their children, or others who handle or consume the placenta)? Should people be permitted to reclaim their placenta over medical providers' objections? There are instances in which the medical team believes the placenta should be submitted to the department of pathology, or at least withheld for a certain period at the hospital, for future testing. Placenta scientist Harvey Kliman believes that all placentas should be stored at medical facilities, creating a placenta archive available for physicians to better care for the birthing parents, their children, and other family members, among other potential uses.³⁹⁰ Placenta analysis can reveal underlying health concerns for both parent and child, explain adverse events during childbirth, and even predict, or help manage future pregnancies.³⁹¹ Currently, in the context of hospital childbirth, the medical team may decide to send a placenta to pathology without a woman's consent.³⁹² Healthcare facilities typically have in-house guidelines for placenta testing in case of certain abnormalities,³⁹³ but some reports suggest that they sometimes

389. *Id.* at 8.

390. See *supra* note 150 and accompanying text (not all proposed uses of these archived placentas would benefit patients and their families as they could also serve as evidence to defend physicians in malpractice suits or in paternity suits and create privacy risks through their retention of children's genetic and other information).

391. Baergen, *supra* note 153 (explaining that examining the placenta provides valuable information on the cause and timing of many adverse events and conditions). As noted earlier, placentas can also be tools in obstetric malpractice litigation. See *supra* note 151 and accompanying text.

392. Placental pathology is used to clarify the causes of adverse pregnancy outcomes. See Gitta Turowski et al., *The Structure and Utility of the Placental Pathology Report*, 126 J. PATHOLOGY, MICROBIOLOGY & IMMUNOLOGY 638 (2018) (explaining why placentas are sent to pathology, arguing that pathologists write reports using unclear terminology that is hard for clinicians to understand, and noting that "[s]ubmitting all placentas for pathologic examination is not clinically indicated and would be fiscally disastrous for most institutions"); see also Deborah J. Gersell, *ASCP Survey on Placental Examination*, 109 AM. J. CLINICAL PATHOLOGY 127, 127 (1998) (stating that fewer than 25 percent of placentas delivered at institutions are sent to pathology).

393. See Farr et al., *supra* note 67, at 406 tbl.2 (summarizing the nationally accepted guidelines specifying the indications to submit placentas to pathology).

get tested needlessly at the expense of patients and the healthcare system.³⁹⁴ Should birthing parents have the right to decline testing? Further research on the costs and benefits of placenta pathology is required to fully address this issue, but this need not be a zero-sum game. It would be conceivable for pathologists and birth parents to exercise concurrent access over placentas. In cases in which both groups want the placenta, the placenta could be sent to pathology for observation, weighing, and sample excision, before the majority of the tissues were returned to the family still fresh and unfixed within a twenty-four-hour time frame.³⁹⁵

Some may challenge the idea of protecting women's decision-making autonomy over their placentas on the ground that there is no reason to treat placentas differently from other biological materials—for example, blood, skin, saliva, urine, and feces—that are collected by healthcare facilities in the course of diagnostic or therapeutic procedures and used for research, biobanking, medicine, and other purposes. Some may argue that a new choice architecture for placenta would create a slippery slope, as it could be extended to these other materials, making research and medicine more administratively burdensome and expensive.

Yet, several features of the placenta justify giving its producers greater decision-making authority. First, patients relinquishing other bodily materials have no personal use for them, except for rare cases in which for idiosyncratic or cultural reasons they wish to recover a body part such as an amputated limb.³⁹⁶ By contrast, the intense spiritual, cultural, or religious interest some people have in placentas warrants a right for patients not only to access their placentas upon request, but also to be provided with information on placental uses and value that may facilitate an informed decision-making process. Second, this right may not be as onerous as it seems given the rarity of its exercise. Placentas are not collected as commonly as other biological materials, and the majority of patients

394. Dr. Redline, *Placental Pathology: Is it Time to Get Serious?*, CONTEMP. OB/GYN (Feb. 1, 2014), <https://www.contemporaryobgyn.net/modern-medicine-cases/placental-pathology-it-time-get-serious> [https://perma.cc/7GD3-VUDT].

395. Pathologists routinely perform rapid microscopic analyses of specimens or cryosections in the course of surgeries, so there is no technical obstacle to a fast-paced turnaround for placenta pathology. See Anthony A. Gal & Philip T. Cagle, *The 100-Year Anniversary of the Description of the Frozen Section Procedure*, 294 J. AM. MED. ASS'N 3135 (2005) (detailing the history and practice of the frozen section procedure). This would require adequate personnel, resources, and policies.

396. *Browning v. Norton-Children's Hosp.*, 504 S.W.2d 713, 715 (Ky. Ct. App. 1974) (finding that hospital properly disposed of an amputated leg by cremation in the absence of any indication that the patients desired otherwise); see also Blake A. Gibson & Richard E. Sobonya, *Patients Who Take Home Their Surgical Pathology Specimens: A Preliminary Study*, 6 ACAD. PATHOLOGY 1 (2019) (one of the first studies of the prevalence and motivation behind patients' requests that their tissues be returned to them).

do not want their placentas back.³⁹⁷ Even people who are interested in claiming their placenta will have only a limited ability to exercise the right repeatedly, given that in the course of their reproductive lives they are unlikely to be pregnant more than a handful of times. Placentas are therefore quite unlike biological samples such as blood, urine, skin, saliva, or feces, which could theoretically be collected and reclaimed thousands of times by the same person. With placentas, there is little room for the odd patient to drastically increase costs, providing an intrinsic barrier to a potential ripple effect.

B. Framing Consent

As Elizabeth Emens has shown in the context of name changing,³⁹⁸ “framing rules” may affect certain decisions in which, like placenta retention, “social conventions, rather than legal rules, seem largely to drive behavior.”³⁹⁹ Framing rules focus on how the question is asked, not on what the rules are.⁴⁰⁰ It is therefore important to reflect upon the best way to frame informed consent procedures for placenta collection and donation. For instance, if pregnant people are told nothing about the placenta or just that it is a waste product of pregnancy on par with blood and other body fluids, they may be more likely to donate it. By contrast, merely asking a pregnant person whether they intend to request the release of their placenta or informing them that they have the right to do so could lead them to believe that a recommended action is implied.

In other words, how can people’s consent to the use of their placenta be made fully informed and voluntary? Radhika Rao notes that “[t]he true challenge of informed consent is that this venerable doctrine often functions as a charade, a collective fiction which thinly masks the uncomfortable fact that the subjects of human research are not actually afforded full information regarding the types of research that may be contemplated, nor do they provide meaningful consent.”⁴⁰¹ The few studies that investigate perceptions about placenta donation suggest that women are quite willing to donate so long as they are asked in a timely fashion, by the right person, and provided with adequate information.⁴⁰² But this

397. See Baergen, Thaker & Heller, *supra* note 322, at 327 (stating that the main reason why some of the hospitals they surveyed did not release placentas was “due to lack of requests”).

398. See Elizabeth F. Emens, *Changing Name Changing: Framing Rules and the Future of Marital Names*, 74 U. CHI. L. REV. 761, 839-54 (2007).

399. See *id.* at 839.

400. See *id.* at 840.

401. See Rao, *supra* note 26, at 438.

402. The studies were conducted in Brazil, Denmark, Finland, and the United States. See A. Halkoaho et al., *Ethical Aspects of Human Placental Perfusion: Interviews of the Mothers Donating Placenta*, 31 PLACENTA 686, 689 (2010) (interviewing Finnish women who donated their placentas for scientific studies); Claudia A. Kozinetz et al., *Consenting Postpartum Women for Use of Routinely Collected Biospecimens and/or Future Biospecimen Collection*, 7 J. COMMUNITY GENETICS 153, 154 (2016) (Texas study of postpartum women’s willingness to consent to future and residual

conclusion cannot be generalized to cultural contexts in which the placenta has a special cultural and religious value, calling for follow-up research among different populations.⁴⁰³ Assuming that patients have a real choice between reclaiming their placenta, having it disposed of, archiving it at the facility, or donating it, what should be the required framing in terms of timing, identity of those asking for consent, and informational content? The next subsections address each of these factors in turn.

1. The Timing of Consent

In her 2012–2013 Brazilian study, Rebecca Yoshizawa reported that 60% of the women she surveyed “preferred to be approached about donation during prenatal appointments.”⁴⁰⁴ Similarly, Arja Halkoaho and colleagues’ 2008–2009 Finnish study suggests that waiting until delivery to ask for consent is inadequate. They emphasize that due to the nature of labor—which can be long, absorbing, painful, and emotional—there was sometimes no time at all to discuss the research project with potential donors and even when there was, women “gave their consent almost immediately . . . there was usually no in-depth conversation between the mother and the midwife. Most mothers did not ask any questions, and those who did only had basic queries such as where would the placenta go and what would it be studied for.”⁴⁰⁵ Waiting until after labor is over is not preferable. A study conducted in Texas on seventy-two postpartum women looked at “the feasibility and acceptability of consenting women post-delivery before hospital discharge.”⁴⁰⁶ The authors found that the majority of women consented,⁴⁰⁷ but a major limitation is that the study was conducted on a vulnerable demographic of women more likely to consent—58% were Latinx, 61% had no college education, 58% were unmarried, 40% had an annual family income below \$30,000, and 49% were unemployed before delivery.⁴⁰⁸ Based on these studies, I would favor a regime in which pregnant people were informed

collection of biospecimens); Uffe Lind, Tina Mose & Lisbeth E. Knudsen, *Participation in Environmental Health Research by Placenta Donation—A Perception Study*, 6 ENVTL. HEALTH 36 (2007) (interviewing Danish women who donated their placentas for scientific studies); Yoshizawa et al., *supra* note 15, at 80 (empirical study in 2012–2013 surveying public perspectives of placentas and placenta donation among Brazilian women postpartum).

403. Sandra Crouse Quinn et al., *Improving Informed Consent with Minority Participants: Results from Researcher and Community Surveys*, 7 J. EMPIRICAL RES. ON HUM. RES. ETHICS 44, 45 (2012) (arguing that practices of informed consent should be adapted to and reflect the preferences of the groups involved).

404. Yoshizawa et al., *supra* note 15, at 79.

405. Arja Halkoaho et al., *Views of Midwives About Ethical Aspects of Participation in Placental Perfusion Studies*, 28 MIDWIFERY 131, 133 (2012).

406. Kozinetz et al., *supra* note 402, at 154.

407. *Id.*

408. *Id.* at 153.

about placenta collection, storage, and donation during prenatal appointments, starting as early as the first trimester of pregnancy. Sometimes, the timing of consent will need to occur later in pregnancy, for example, when the placenta is collected to study a condition that developed or was discovered closer to delivery, such as intrauterine growth restriction, preeclampsia, or premature labor. But even then, if patients had been aware of the practice of collecting placentas for various purposes since the first months of their pregnancy, they would likely be better informed about their options and the costs and benefits.

2. The Identity of Those Asking for Consent

By whom should consent be sought? Yoshizawa reports that in her Brazilian survey “having their doctor invite them to donate their placenta is respondents’ preference (78%) over any other person and in particular, the vast majority did not support having the researcher directly approach them.”⁴⁰⁹ In placental studies conducted in countries where obstetric care is provided by midwives, it is common for midwives to act as the recruiters.⁴¹⁰ In the United States, the conversation should be initiated by the pregnant person’s providers, be they OBGYNs or midwives. In addition, in cultural contexts in which the placenta has a ritual meaning for the well-being and future of the entire family or community—not just the birthing parent and their baby—a conversation should be initiated as to whether consent should be solicited from the entire group rather than the individual patient.

3. The Information Provided

How much and which information should be communicated? As Yoshizawa and her colleagues’ research shows, “[d]isinterest in seeing the placenta at birth, and a lack of spiritual valuation, does not mean women are indifferent to the organ or its final fate.”⁴¹¹ According to research conducted in England in 2009–2010, people surveyed about their attitudes toward cord-blood banking thought that pregnant women had a right to know the value of cord blood and a right to donate it.⁴¹² Providing similar information on the placenta would not require that medical providers endorse any form of placenta self-consumption or use, but ensure that all patients are aware of its value. The donation solicitation process

409. Yoshizawa et al., *supra* note 15, at 79.

410. Halkoaho et al., *supra* note 402, at 690.

411. Yoshizawa et al., *supra* note 15, at 81.

412. Laura L. Machin, Nik Brown & Danae McLeod, *Giving to Receive? The Right to Donate in Umbilical Cord Blood Banking for Stem Cell Therapies*, 104 HEALTH POL’Y 296, 296 (2012).

should include information on the projected purpose of the placental tissue and its commercial dimension, if any.⁴¹³

The risks and benefits of placenta donation should also be discussed. Other-regarding benefits such as supporting research and contributing to medicine and patient care are already part of public discourse on placenta donation. By contrast, the question whether donors themselves reap any medical or other benefits is rarely addressed. Yet, there is the possibility of a two-way relationship of reciprocal exchange between placenta scientists and clinicians and donors since placental tissues are highly useful to investigate the etiology and treatment of negative pregnancy outcomes. Patients who experience pregnancy loss or complications, or who seek terminations motivated by fetal abnormalities in particular may stand to gain from placenta research on how to improve their outcomes. Similarly, placental examination can be useful in the diagnosis and treatment of children who develop certain illnesses or disabilities.⁴¹⁴

The risks of donating placentas (or allowing facilities to archive them) are seldom discussed. This may be because, unlike other types of living donations, there are no physical risks involved. Placentas are temporary organs naturally expelled from the body. A donor does not risk pain, complications, or future health problems. There is no research, however, assessing whether, as in living organ donation, there are psychological risks in donating placental tissue, such as sadness, anxiety, or resentment. In addition, other types of risks are associated with placenta donation. Similar to organ and tissue donation, physicians' reputational or economic interest in the value of placental tissue may influence the quality of care women receive.⁴¹⁵ There is also a privacy risk for both donors and their children. As Yoshizawa has pointed out, "if the placenta is indeed a 'diary' of pregnancy, potentially-sensitive information might be obtained."⁴¹⁶ In addition to information gathered from the analysis of the placental tissue, the screening of donors and the creation of individual identifiers generate medical information.⁴¹⁷

To conclude, not only should pregnant people be consulted before their placentas become usable by third parties, but the consent procedure should be

413. One complication is that biospecimens are sometimes collected for one use and later repurposed. As a solution, some scholars have proposed the legal recognition of new forms of consent, such as the idea of "dynamic consent," which relies on new information technologies to keep researchers and participants in touch via a personalized communication interface and thereby allows researchers to change their research uses and participants to re-consent. See Jane Kaye et al., *Dynamic Consent: A Patient Interface for Twenty-First Century Research Networks*, 23 EUR. J. HUM. GENETICS 141, 141 (2015).

414. See *supra* note 387 and accompanying text.

415. *Who Should Profit from the Economic Value of Human Tissue?: An Ethical Analysis*, 1 CODE MED. ETHICS REP. 124 (1990).

416. Yoshizawa, *supra* note 29, at 11.

417. See Burton et al., *supra* note 165, at 18.

carefully redesigned with an eye to protecting their autonomy through proper timing, interactions, and information.

C. Should Placenta Donors Be Compensated?

Semen donors, egg donors, feces donors,⁴¹⁸ and blood donors⁴¹⁹ are compensated, but organ and tissue donors are prohibited from earning any form of payment under state and federal law.⁴²⁰ Where should the placenta stand? While people give their placental tissue free of charge, it may be appraised and exchanged for money, not unlike what can be observed with other organs and tissues.⁴²¹ The healthcare centers where pregnant patients are treated, the medical transportation companies that transport placentas, the research institutions, tissue banks, procurement organizations, or biotech companies that process, test, and distribute the placentas can each attach charges to it. Why should these organizations be compensated for their work when donors themselves are not?⁴²²

This disparity calls into question why, in the few states such as Connecticut, Oregon, and Texas that explicitly allow women to obtain the release of their placentas from healthcare facilities, a standard precondition is that the placenta will be for “personal use” and not for sale.⁴²³ In Texas, the stipulation appears

418. Rachel Feltman, *You Can Earn \$13,000 a Year Selling Your Poop*, WASH. POST (Jan. 29, 2015, 7:00 AM MST) <https://www.washingtonpost.com/news/speaking-of-science/wp/2015/01/29/you-can-earn-13000-a-year-selling-your-poop> [<https://perma.cc/M9VS-7PKZ>].

419. See Sophia Chase, *The Bloody Truth: Examining America's Blood Industry and its Tort Liability Through the Arkansas Prison Plasma Scandal*, 3 WM. & MARY BUS. L. REV. 597, 602 (2012).

420. The National Organ Transplant Act (NOTA) makes the selling of human organs a federal crime. National Organ Transplant Act, Pub. L. No. 98-507, 98 Stat. 2339 (codified as amended at 42 U.S.C. §§ 273–274(e) (1988)). But see Russell Korobkin, “No Compensation” or “Pro Compensation”: *Moore v. Regents and Default Rules for Human Tissue Donations*, 40 J. HEALTH L. 1, 6 (2007) (arguing that NOTA’s language allows researchers to sell protected organs for research purposes without offending the terms or purpose of the statute). The Uniform Anatomical Gift Act (UAGA), which has been enacted in some form by all fifty states, provides for the charitable disposition of the corpse for research and of organs for transplant. See REV. UNIF. ANATOMICAL GIFT ACT (UNIF. LAW COMM’N 2006).

421. Michele Goodwin, *Expressive Minimalism and Fuzzy Signals: The Judiciary and the Role of Law*, 84 CHI.-KENT L. REV. 19, 49 (2009); see also J. Randall Boyer, *Gifts of the Heart . . . and Other Tissues: Legalizing the Sale of Human Organs and Tissues*, 2012 BYU L. REV. 313, 314 (2012) (critiquing the fact that the “same federal and state laws [NOTA and UAGA] that prohibit donors from receiving compensation for their organs and tissues facilitate this industry by providing recovery of costs to anyone who removes, stores, transports, processes, or transplants the organ or tissue”); *supra* Part II.A.3.i.a. (noting that the placenta does not meet the federal definition of organs).

422. Journalist Matilda Battersby posed this question in 2017. Battersby, *supra* note 235.

423. See CONN. GEN. STAT. § 19A-490V (2018) (providing that “a hospital may allow a woman . . . to take possession of and remove from the hospital the placenta if: . . . [it is] for personal use. A person removing a placenta from a hospital under this section may only retain the placenta for personal use and may not sell the placenta”); OR. ADMIN. R. 333-056-0045 (2018) (requiring that the woman obtaining the release of her placenta sign a form containing “[a]n attestation . . . that the placenta will not be used for commercial purposes”); TEX. HEALTH & SAFETY CODE ANN. §

all the more one-sided since another statutory provision exempts from disposal requirements “placentas designated for sale and obtained from a licensed hospital or a licensed birthing center.”⁴²⁴ This specification suggests that placentas can be sold so long as the seller is not the donor themselves. This legally mandated “giftification”⁴²⁵ of the placenta contributes to the invisibility of the reproductive labor involved in producing it. In response to this tendency for bodies coded as female to be treated as a source of free biological materials, Melinda Cooper and Catherine Waldby have conceptualized women’s embodied participation in research and medicine—be it as tissue donors, clinical trial participants, experimental subjects, or surrogates—as a form of “clinical labor.”⁴²⁶ They point out that donating tissue is work and that donors should be viewed as workers rather than volunteers. Under this view, placenta producers should be compensated.

Several challenges could be raised against this view. First, opponents may point to the risk of exploitation, which have been discussed at length in the context of organ donation. But given the low risks involved in placenta donation and the lack of interest many people have in keeping it for themselves, introducing compensation is unlikely, in and of itself, to lead to exploitation. A related concern would be that the people most likely to be motivated by financial incentives will be those constrained by socioeconomic circumstances, who may decide to get pregnant for the purpose of selling their placenta. An obvious rejoinder is that the monetary benefit for a single placenta would have to be extremely high to offset the costs, risks, and burdens of pregnancy, making this prospect highly implausible.

Second, paying donors may drive up the cost of socially useful activities such as research and medicine. This is a realistic possibility, but there may be ways to offset the hike. First, it is likely that not all donors would accept the compensation. Some may prefer to donate for free, similar to people who give their milk free of charge rather than selling it.⁴²⁷ Additionally, compensation

172.002(a)(2)(B), (b) (West 2018) (allowing women to take possession of their placenta and requiring they sign a form acknowledging that “the placenta is for personal use. A person removing a placenta from a hospital or birthing center under this section may only retain the placenta for personal use and may not sell the placenta”).

424. 25 TEX. ADMIN. CODE § 138.3 (2018).

425. See generally Marisa Gerstein Pineau, *Liquid Gold: Breast Milk Banking in the United States* 1 (2012) (unpublished Ph.D. dissertation, University of California Los Angeles) (on file with author) (arguing that over the course of the twentieth century, human milk underwent a process of “giftification,” whereby most milk banks no longer pay donors for their milk even though they themselves dispense it for a hefty fee to hospitals and a few outpatients).

426. MELINDA COOPER & CATHERINE WALDBY, *CLINICAL LABOR: TISSUE DONORS AND RESEARCH SUBJECTS IN THE GLOBAL BIOECONOMY* 17 (2014).

427. See Mathilde Cohen, *Should Human Milk Be Regulated?*, 9 U.C. IRVINE, L. REV. 557, 617 (2019) (arguing that people who supply milk banks and companies with milk should have the option to be paid a living wage).

could be structured in a way that minimizes the rise in research and care expenditures. For example, in profit-sharing schemes, profits from the commercial use of human tissue and its products are shared with patients in accordance with contractual agreements. Physicians, researchers, biobanks, and other organizations may offer patients a small percentage of any profits that are realized on products derived from the patient's tissues. Compensation in the form of reciprocity could also be substituted for cash payments. Empirical research on placenta donation indicates that reciprocity is an important factor for donors, particularly in countries with universal health care. A 2007 study of Danish women donating placentas for medical research revealed that participants experienced donation as a way of "giving something back to the Danish health care system."⁴²⁸ A Scottish study of a population genetic database involving the collection of thousands of placentas resulted in similar findings. Participants felt that donation "was an opportunity 'to put something back in' for care . . . received from the UK National Health Service."⁴²⁹ Donors exhibited "a desire to reciprocate" as well as "a wish for reciprocation."⁴³⁰ In the United States, where gynecological, prenatal, obstetric, and postpartum care can be prohibitively expensive and lagging in quality, especially for the most vulnerable populations of women,⁴³¹ offering donors access to more affordable and higher quality care could benefit them and their children as well as providers and researchers.⁴³²

D. Regulating Placenta-Based Products

Given the potential harmful effects of some of the placenta-based cosmetic products, a very different regime is required for personal care products—one that is less about choice and more about consumer protection and changing norms or behaviors of corporate actors. Federal and state laws regulate the placenta based on its use—as waste to be disposed of, research subject, tissue used for therapeutic purpose, dietary ingredient or food, and cosmetic ingredient.

428. Lind, Mose & Knudsen, *supra* note 402, at 4 ("Since the Danish health care system is funded through taxes collected by the Danish state, health care in Denmark is often perceived as both free and as a collective project. Some of the informants thus stressed that participating was a way of giving something back to the Danish health care system.").

429. Gillian Haddow, "We Only Did It Because He Asked Us": Gendered Accounts of Participation in a Population Genetic Data Collection, 69 SOC. SCI. & MED. 1010, 1013 (2009).

430. *Id.*

431. See Linda Villarosa, *Why America's Black Mothers and Babies Are in a Life-or-Death Crisis*, N.Y. TIMES (Apr. 11, 2018), <https://www.nytimes.com/2018/04/11/magazine/black-mothers-babies-death-maternal-mortality.html> [<https://perma.cc/WYE7-X4MW>] (exposing some of the inequities that lead to the glaring racial and ethnic disparities in maternal and neonatal health outcomes in the United States).

432. *But see* Goodwin, *supra* note 378, at 1235 (indicating that some medical practitioners condition treatment upon patients' waiving their rights to their tissues). This scenario should be avoided in the imagined compensation scheme by requiring that healthcare facilities deliver care regardless of a patient's decision about their placenta.

Consumers of placenta-based drugs and therapies enjoy some protection under food and drug law even if this body of law may be underenforced.⁴³³ However, consumers of *cosmetic* placental products are especially vulnerable. This is due in part to the general insufficiency of cosmetic regulation by the FDA under the FD&C Act.⁴³⁴ Under the FD&C Act, cosmetic products and ingredients, other than color additives, do not need FDA approval before they go on the market.⁴³⁵ It is manufacturers' responsibility to ensure the safety of their ingredients. The only requirement is that the cosmetic must not be adulterated or misbranded.⁴³⁶

In 2002, the Cosmetic Ingredient Review (CIR) Expert Panel published their assessment of placenta-derived ingredients (human and animal) in the *International Journal of Toxicology*.⁴³⁷ Formed in 1976 as a joint effort by government, industry, and consumer groups, the CIR is one of the cosmetic industry's self-regulatory programs that reviews and assesses the safety of ingredients used in cosmetics and publishes the results in peer-reviewed literature.⁴³⁸ The CIR Expert Panel concluded that the data were insufficient to make a determination of safety.⁴³⁹ It has not looked at placenta-derived ingredients since. Accordingly, the safe use of these ingredients in cosmetics is not supported. As noted earlier, in 1994 the FDA recommended that placenta-based ingredients be identified by a name other than "placental extract" so as to describe them more accurately because consumers associate the name "placental extract" with a therapeutic use or some biological activity.⁴⁴⁰ The CIR Expert Panel 2002 review reiterated the message by advising industry that cosmetic formulations should *not* be identified as containing "human placental extract" or "placental extract" so as to comply with FDA guidelines.⁴⁴¹ The result is a lack of clarity and inadequate labeling for consumers who may not be able to tell whether a product contains placenta.

A first step toward protecting consumers would be to require transparency by compelling manufacturers to list any ingredients derived from human or animal placentas as such. In light of the studies mentioned above on the dangers of placenta-based cosmetics, FDA should also continue to pursue enforcement

433. See *supra* notes 249-55 and accompanying text.

434. See Boyd, *supra* note 301 (critiquing this lack of regulation from an intersectional feminist perspective).

435. See Gabrielle Eriquez, *Makeup Call: How Cosmetic Product Use Affects Women Absent Federal Regulation*, 25 WM. & MARY J. WOMEN & L. 221, 223 (2018).

436. *Id.*

437. Nair & Elmore, *supra* note 142.

438. See Ivan J. Boyer et al., *The Cosmetic Ingredient Review Program—Expert Safety Assessments of Cosmetic Ingredients in an Open Forum*, 36 INT'L J. TOXICOLOGY 5S (2017) (presenting the history and role of CIR).

439. Nair & Elmore, *supra* note 142, at 90.

440. COSMETIC HANDBOOK, *supra* note 313, at 12-13.

441. Nair & Elmore, *supra* note 142, at 89.

actions against products established to be harmful even when used as intended and ban placenta-based products, pending the result of new clinical studies on the safety of placenta-based ingredients conducted by independent researchers or by the agency. In March of 2019, the latest version of the Personal Care Safety Act was introduced in the Senate. If adopted, the Act would go a long way toward protecting consumers against all dangerous cosmetics by, *inter alia*, requiring the FDA to review at least five cosmetic ingredients annually for safety, imposing “good manufacturing practices,” mandating adverse event reporting, and instituting more extensive labeling requirements, including ingredients not appropriate for children or for professional use only.⁴⁴²

In contrast to this pro-regulatory stance as applied to placenta-based cosmetics, the current non-interventionist FDA regulation of placenta self-consumption and encapsulation is satisfactory. Consuming one’s own placenta is not risk-free, but the risks which have been documented so far do not warrant intruding into birthing parents’ freedom of choice.⁴⁴³ In addition, contrary to placenta-based personal care products, which are used over long periods of time (sometimes years) and by multiple consumers, placentophagy is limited in time and number of ingestion opportunities, which may lower the risks of adverse hormonal effects, if any. People who engage in placentophagy rarely share their placenta products with others, and even more rarely with children, who may be more vulnerable to potential harmful hormonal effects.⁴⁴⁴ As for encapsulators, regulation would ensure that they are properly trained and follow consistent guidelines, increasing the safety of placenta pills and other placental products for self-consumption. But encapsulators are not in the business of putting products on the marketplace for the general public to purchase. They are hired by individuals to prepare their own placentas for self-consumption. Any potentially harmful product would in principle only be consumed by birth parents themselves. This is a case where the risk is one of self-harm rather than harm to others, justifying lenient legal interventions, if any, especially considering that placenta encapsulators already self-regulate.⁴⁴⁵

CONCLUSION

This Article argues that the under- and overregulation of the placenta creates a significant reproductive justice issue. The inequities at stake in placenta

442. Personal Care Products Safety Act, S. 726, 116th Cong. (2019).

443. *See supra* note 67 and accompanying text.

444. *But see Placenta Tincture, TREE OF LIFE PLACENTA SERV.*, <https://www.portlandplacentaservices.com/other-placenta-remedies--services.html> [https://perma.cc/53RR-JUNA] (recommending giving drops of placenta tincture to children when they are “getting sick or in a time of transition”).

445. *See supra* Part II.A.3.

regulation can be summed up in the following supply and demand chain. Pregnant people produce placental tissue through their reproductive labor. Generally constructed by the law as waste products, placentas may be simultaneously inaccessible to postpartum patients on the ground that they are infectious and available for use by third parties on the ground that they are discarded. In states seeking to ban or restrict abortions, however, patients may have more ready access to their placenta following an abortion or a miscarriage than after the delivery of a baby by reason of fetal remains being categorized as cadavers of born persons whose remains must be dignified and cannot be classified as waste. Finally, while some patients may be denied access to their own placentas, others may purchase poorly regulated placenta-based cosmetics and therapies.

To curb this cycle, this Article proposes that pregnant patients' right to choose what to do with their placenta should be legally protected and that placenta-based cosmetics should be regulated more strictly. To develop a comprehensive legal regime pertaining to placentas, data must be collected on the ins and outs of current placental economies, as there is much we do not currently know about how placentas are collected, transformed, marketed, labeled, and more. This Article has broader implications for the law of the body in general, as it shows that placentas disrupt some of the assumptions underpinning the functioning and regulation of the bioeconomy. Placentas contradict the happy story according to which, after diagnostic or therapeutic procedures, patients do not think about what happens to their tissues, which can therefore be retained as waste and utilized without obtaining patient consent or providing compensation. The idea of protecting patients' autonomy over their placentas could thus serve as a blueprint for exploring whether and how similar protections should be extended to other body parts and biological materials.

